SUBCHAPTER B—MEDICARE PROGRAM

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FEDERALLY QUALIFIED HEALTH CENTER SERVICES

PAYMENT FOR RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES

AUTHORITY: Secs. 1102, 1861, 1862(a), 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

Subpart A [Reserved]

Subpart B—Medical Services Coverage Decisions That Relate to Health Care Technology

AUTHORITY: Secs. 1102, 1862 and 1871 of the Social Security Act as amended (42 U.S.C.1302, 1395y, and 1395hh).

SOURCE: 60 FR 48423, Sept. 19, 1995, unless otherwise noted.

§ 405.201 Scope of subpart and definitions.

(a) *Scope.* This subpart establishes that—

(1) CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions; and

(2) CMS may consider for Medicare coverage certain devices with an FDA-approved investigational device exemption (IDE) that have been categorized as non-experimental/investigational (Category B).

(b) *Definitions.* As used in this subpart—

Class I refers to devices for which the general controls of the Food, Drug, and Cosmetic Act, such as adherence to good manufacturing practice regulations, are sufficient to provide a reasonable assurance of safety and effectiveness.

Class II refers to devices that, in addition to general controls, require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness.

Class III refers to devices that cannot be classified into Class I or Class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require premarket approval.

Contractors refers to carriers, fiscal intermediaries, and other entities that contract with CMS to review and adjudicate claims for Medicare services.

Experimental/investigational (Category A) device refers to an innovative device believed to be in Class III for which ''absolute risk'' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective).

IDE stands for investigational device exemption. An FDA-approved IDE application permits a device, which would otherwise be subject to marketing clearance, to be shipped lawfully for the purpose of conducting a clinical trial in accordance with 21 U.S.C. 360j(g) and 21 CFR parts 812 and 813.

Non-experimental/investigational (Category B) device refers to a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

PMA stands for ''premarket approval'' and refers to a marketing application for a Class III device, which includes all information submitted with or incorporated by reference in the application in accordance with 21 U.S.C. 360e and 360j and 21 CFR 814.3(e).

Sponsor refers to a person or entity that initiates, but does not conduct, an investigation under an IDE.

§ 405.203 FDA categorization of investigational devices.

(a) The FDA assigns a device with an FDA-approved IDE to one of two categories:

(1) Experimental/Investigational (Category A) Devices.

(2) Non-Experimental/Investigational (Category B) Devices.

(b) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as experimental/investigational (Category A) or non-experimental/investigational (Category B).

(c) CMS uses the categorization of the device as a factor in making Medicare coverage decisions.

§ 405.205 Coverage of a non-experimental/investigational (Category B) device.

(a) For any device that meets the requirements of the exception at §411.15(o) of this chapter, the following procedures apply:

(1) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as non-experimental/investigational (Category B).

(2) CMS uses the categorization of the device as a factor in making Medicare coverage decisions.

(b) If the FDA becomes aware that a categorized device no longer meets the requirements of the exception at §411.15(o) of this chapter, the FDA notifies the sponsor and CMS and the procedures described in paragraph (a)(2) of this section apply.

§ 405.207 Services related to a noncovered device.

(a) *When payment is not made.* Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not ''reasonable'' and ''necessary'' under section 1862(a)(1)(A) of the Act or because it is excluded from coverage for other reasons. These services include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related noncovered services.

(b) *When payment is made.* Medicare payment may be made for—

(1) Covered services to treat a condition or complication that arises due to the use of a noncovered device or a noncovered device-related service; or

(2) Routine care services related to experimental/investigational (Category A) devices as defined in §405.201(b); and furnished in conjunction with an FDA-approved clinical trial. The trial must meet criteria established through the national coverage determination process; and if the trial is initiated before January 1, 2010, the device must be determined as intended for use in the diagnosis, monitoring or treatment of an immediately life-threatening disease or condition.

(3) Routine care services related to a non-experimental/investigational (Category B) device defined in §405.201(b) that is furnished in conjunction with an FDA-approved clinical trial.

[60 FR 48423, Sept. 19, 1995, as amended at 69 FR 66420, Nov. 15, 2004]

§ 405.209 Payment for a non-experimental/investigational (Category B) device.

Payment under Medicare for a non-experimental/investigational (Category B) device is based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA.

§ 405.211 Procedures for Medicare contractors in making coverage decisions for a non-experimental/investigational (Category B) device.

(a) *General rule.* In their review of claims for payment, Medicare contractors are bound by the statute, regulations, and all CMS administrative issuances, including all national coverage decisions.

(b) *Potentially covered non-experimental/investigational (Category B) devices.* Medicare contractors may approve coverage for any device with an FDA-approved IDE categorized as a non-experimental/investigational (Category B) device if all other coverage requirements are met.

(c) *Other considerations.* Medicare contractors must consider whether any restrictions concerning site of service, indications for use, or any other list of conditions for coverage have been placed on the device's use.

§ 405.213 Re-evaluation of a device categorization.

(a) *General rules.* (1) Any sponsor that does not agree with an FDA decision that categorizes its device as experimental/investigational (Category A) may request re-evaluation of the categorization decision.

(2) A sponsor may request review by CMS only after the requirements of paragraph (b) of this section are met.

(3) No reviews other than those described in paragraphs (b) and (c) of this section are available to the sponsor.

(4) Neither the FDA original categorization or re-evaluation (described in paragraph (b) of this section) nor

CMS's review (described in paragraph (c) of this section) constitute an initial determination for purposes of the Medicare appeals processes under part 405, subpart G or subpart H, or parts 417, 473, or 498 of this chapter.

(b) *Request to FDA.* A sponsor that does not agree with the FDA's categorization of its device may submit a written request to the FDA at any time requesting re-evaluation of its original categorization decision, together with any information and rationale that it believes support recategorization. The FDA notifies both CMS and the sponsor of its decision.

(c) *Request to CMS.* If the FDA does not agree to recategorize the device, the sponsor may seek review from CMS. A device sponsor must submit its request in writing to CMS. CMS obtains copies of relevant portions of the application, the original categorization decision, and supplementary materials. CMS reviews all material submitted by the sponsor and the FDA's recommendation. CMS reviews only information in the FDA record to determine whether to change the categorization of the device. CMS issues a written decision and notifies the sponsor of the IDE and the FDA.

§ 405.215 Confidential commercial and trade secret information.

To the extent that CMS relies on confidential commercial or trade secret information in any judicial proceeding, CMS will maintain confidentiality of the information in accordance with Federal law.

Subpart C—Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans

AUTHORITY: Secs. 1102, 1815, 1833, 1842, 1866, 1870, 1871, 1879, and 1892 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395cc, 1395gg, 1395hh, 1395pp, and 1395ccc) and 31 U.S.C. 3711.

SOURCE: 31 FR 13534, Oct. 20, 1966, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

GENERAL PROVISIONS

§ 405.301 Scope of subpart.

This subpart sets forth the policies and procedures for handling of incorrect payments and recovery of overpayments.

[54 FR 41733, Oct. 11, 1989]

LIABILITY FOR PAYMENTS TO PROVIDERS OR SUPPLIERS AND HANDLING OF INCORRECT PAYMENTS

§ 405.350 Individual's liability for payments made to providers and other persons for items and services furnished the individual.

Any payment made under title XVIII of the Act to any provider of services or other person with respect to any item or service furnished an individual shall be regarded as a payment to the individual, and adjustment shall be made pursuant to §§ 405.352 through 405.358 where:

(a) More than the correct amount is paid to a provider of services or other person and the Secretary determines that:

(1) Within a reasonable period of time, the excess over the correct amount cannot be recouped from the provider of services or other person, or

(2) The provider of services or other person was without fault with respect to the payment of such excess over the correct amount, or

(b) A payment has been made under the provisions described in section 1814(e) of the Act, to a provider of services for items and services furnished the individual.

(c) For purposes of paragraph (a)(2) of this section, a provider of services or other person shall, in the absence of evidence to the contrary, be deemed to be without fault if the determination of the carrier, the intermediary, or the Centers for Medicare & Medicaid Services that more than the correct amount was paid was made subsequent to the third year following the year in which notice was sent to such individual that such amount had been paid.

[41 FR 1492, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 61 FR 49271, Sept. 19, 1996]

§ 405.351 Incorrect payments for which the individual is not liable.

Where an incorrect payment has been made to a provider of services or other person, the individual is liable only to the extent that he has benefited from such payment.

§ 405.352 Adjustment of title XVIII incorrect payments.

Where an individual is liable for an incorrect payment (i.e., a payment made under § 405.350(a) or § 405.350(b)) adjustment is made (to the extent of such liability) by:

(a) Decreasing any payment under title II of the Act, or under the Railroad Retirement Act of 1937, to which the individual is entitled; or

(b) In the event of the individual's death before adjustment is completed, by decreasing any payment under title II of the Act, or under the Railroad Retirement Act of 1937 payable to the estate of the individual or to any other person, that are based on the individual's earnings record (or compensation).

[31 FR 13534, Oct. 20, 1966, as amended by 41 FR 1492, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.353 Certification of amount that will be adjusted against individual title II or railroad retirement benefits.

As soon as practicable after any adjustment is determined to be necessary, the Secretary, for purposes of this subpart, shall certify the amount of the overpayment or payment (see § 405.350) with respect to which the adjustment is to be made. If the adjustment is to be made by decreasing subsequent payments under the Railroad Retirement Act of 1937, such certification shall be made to the Railroad Retirement Board.

§ 405.354 Procedures for adjustment or recovery—title II beneficiary.

The procedures applied in making an adjustment or recovery in the case of a title II beneficiary are the applicable procedures of 20 CFR 404.502.

[31 FR 13534, Oct. 20, 1966, as amended at 32 FR 18027, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.355 Waiver of adjustment or recovery.

(a) The provisions of § 405.352 may not be applied and there may be no adjustment or recovery of an incorrect payment (i.e., a payment made under § 405.350(a) or § 405.350(b)) in any case where such incorrect payment has been made with respect to an individual who is without fault, or where such adjustment or recovery would be made by decreasing payments to which another person who is without fault is entitled as provided in section 1870(b) of the Act where such adjustment or recovery would defeat the purpose of title II or title XVIII of the Act or would be against equity and good conscience. (See 20 CFR 404.509 and 404.512.)

(b) Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as may be determined to be inconsistent with the purposes of Title XVIII of the Act) against an individual who is without fault shall be deemed to be against equity and good conscience if the determination that such payment was incorrect was made subsequent to the third year following the year in which notice of such payment was sent to such individual. (See §§ 405.330–405.332 for conditions under which payment may be made for items or services furnished after October 30, 1972 which are noncovered by reasons of § 405.310 (g) and (k).)

[41 FR 1493, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.356 Principles applied in waiver of adjustment or recovery.

The principles applied in determining waiver of adjustment or recovery (§ 405.355) are the applicable principles of § 405.358 and 20 CFR 404.507–404.509, 404.510a, and 404.512.

[61 FR 49271, Sept. 19, 1996]

§ 405.357 Notice of right to waiver consideration.

Whenever an initial determination is made that more than the correct amount of payment has been made, notice of the provisions of section 1870(c) of the Act regarding waiver of adjustment or recovery shall be sent to the overpaid individual and to any other individual against whom adjustment or

recovery of the overpayment is to be effected (see §405.358).

[61 FR 49271, Sept. 19, 1996]

§405.358 When waiver of adjustment or recovery may be applied.

Section 1870(c) of the Act provides that there shall be no adjustment or recovery in any case where an incorrect payment under title XVIII (hospital and supplementary medical insurance benefits) has been made (including a payment under section 1814(e) of the Act with respect to an individual:

(a) Who is without fault, and

(b) Adjustment or recovery would either:

(1) Defeat the purposes of title II or title XVIII of the Act, or

(2) Be against equity and good conscience.

[61 FR 49271, Sept. 19, 1996]

§405.359 Liability of certifying or disbursing officer.

No certifying or disbursing officer shall be held liable for any amount certified or paid by him to any provider of services or other person:

(a) Where the adjustment or recovery of such amount is waived (see §405.355), or

(b) Where adjustment (see §405.352) or recovery is not completed prior to the death of all persons against whose benefits such adjustment is authorized.

SUSPENSION AND RECOUPMENT OF PAYMENT TO PROVIDERS AND SUPPLIERS AND COLLECTION AND COMPROMISE OF OVERPAYMENTS

§405.370 Definitions.

For purposes of this subpart, the following definitions apply:

Offset. The recovery by Medicare of a non-Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness. (Examples are Public Health Service debts or Medicaid debts recovered by CMS).

Recoupment. The recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness.

Suspension of payment. The withholding of payment by an intermediary or carrier from a provider or supplier of an approved Medicare payment amount before a determination of the amount of the overpayment exists.

[61 FR 63745, Dec. 2, 1996]

§405.371 Suspension, offset, and recoupment of Medicare payments to providers and suppliers of services.

(a) *General.* Medicare payments to providers and suppliers, as authorized under this subchapter (excluding payments to beneficiaries), may be—

(1) Suspended, in whole or in part, by CMS, an intermediary, or a carrier if CMS, the intermediary, or the carrier possesses reliable information that an overpayment or fraud or willful misrepresentation exists or that the payments to be made may not be correct, although additional evidence may be needed for a determination; or

(2) Offset or recouped, in whole or in part, by an intermediary or a carrier if the intermediary, carrier, or CMS has determined that the provider or supplier to whom payments are to be made has been overpaid.

(b) *Steps necessary for suspension of payment, offset, and recoupment.* Except as provided in paragraph (c) of this section, CMS, the intermediary, or carrier suspends payments only after it has complied with the procedural requirements set forth at §405.372. The intermediary or carrier offsets or recoups payments only after it has complied with the procedural requirements set forth at §405.373.

(c) *Suspension of payment in the case of unfiled cost reports.* If a provider has failed to timely file an acceptable cost report, payment to the provider is immediately suspended in whole or in part until a cost report is filed and determined by the intermediary to be acceptable. In the case of an unfiled cost report, the provisions of §405.372 do not apply. (See §405.372(a)(2) concerning failure to furnish other information.)

[61 FR 63746, Dec. 2, 1996, as amended at 67 FR 66813, Nov. 1, 2002]

§405.372 Proceeding for suspension of payment.

(a) *Notice of intention to suspend*—(1) *General rule.* Except as provided in paragraphs (a)(2) through (a)(4) of this

section, if the intermediary, carrier, or CMS has determined that a suspension of payments under § 405.371(a)(1) should be put into effect, the intermediary or carrier must notify the provider or supplier of the intention to suspend payments, in whole or in part, and the reasons for making the suspension.

(2) *Failure to furnish information.* The notice requirement of paragraph (a)(1) of this section does not apply if the intermediary or carrier suspends payments to a provider or supplier in accordance with section 1815(a) or section 1833(e) of the Act, respectively, because the provider or supplier has failed to submit information requested by the intermediary or carrier that is needed to determine the amounts due the provider or supplier. (See § 405.371(c) concerning failure to file timely acceptable cost reports.)

(3) *Harm to Trust Funds.* A suspension of payment may be imposed without prior notice if CMS, the intermediary, or carrier determines that the Medicare Trust Funds would be harmed by giving prior notice. CMS may base its determination on an intermediary's or carrier's belief that giving prior notice would hinder the possibility of recovering the money.

(4) *Fraud or misrepresentation.* If the intended suspension of payment involves suspected fraud or misrepresentation, CMS determines whether to impose the suspension and if prior notice is appropriate. CMS directs the intermediary or carrier as to the timing and content of the notification to the provider or supplier. CMS is the real party in interest and is responsible for the decision. CMS may base its decision on information from the intermediary, carrier, law enforcement agencies, or other sources. CMS determines whether the information is reliable.

(b) *Rebuttal*—(1) *If prior notice is required.* If prior notice is required under paragraph (a) of this section, the intermediary or carrier must give the provider or supplier an opportunity for rebuttal in accordance with § 405.374. If a rebuttal statement is received within the specified time period, the suspension of payment goes into effect on the date stated in the notice, and the procedures and provisions set forth in § 405.375 apply. If by the end of the period specified in the notice no statement has been received, the suspension goes into effect automatically, and the procedures set forth in paragraph (c) of this section are followed.

(2) *If prior notice is not required.* If, under the provisions of paragraphs (a)(2) through (a)(4) of this section, a suspension of payment is put into effect without prior notice to the provider or supplier, the intermediary or carrier must, once the suspension is in effect, give the provider or supplier an opportunity to submit a rebuttal statement as to why the suspension should be removed.

(c) *Subsequent action.* If a suspension of payment is put into effect, the intermediary, carrier, or CMS takes timely action after the suspension to obtain the additional evidence it may need to make a determination as to whether an overpayment exists or the payments may be made. The intermediary, carrier, or CMS makes all reasonable efforts to expedite the determination. As soon as the determination is made, the intermediary or carrier informs the provider or supplier and, if appropriate, the suspension is rescinded or any existing recoupment or offset is adjusted to take into account the determination.

(d) *Duration of suspension of payment*—(1) *General rule.* Except as provided in paragraphs (d)(2) and (d)(3) of this section, a suspension of payment is limited to 180 days, starting with the date the suspension begins.

(2) *180-day extension.* (i) An intermediary, a carrier, or, in cases of fraud and misrepresentation, OIG or a law enforcement agency, may request a one-time only extension of the suspension period for up to 180 additional days if it is unable to complete its examination of the information or investigation, as appropriate, within the 180-day time limit. The request must be submitted in writing to CMS.

(ii) Upon receipt of a request for an extension, CMS notifies the provider or supplier of the requested extension. CMS then either extends the suspension of payment for up to an additional 180 days or determines that the suspended payments are to be released to the provider or supplier.

(3) *Exceptions to the time limits.* (i) The time limits specified in paragraphs (d)(1) and (d)(2) of this section do not apply if the case has been referred to, and is being considered by, the OIG for administrative action (for example, civil money penalties).

(ii) CMS may grant an extension in addition to the extension provided under paragraph (d)(2) of this section if the Department of Justice submits a written request to CMS that the suspension of payment be continued based on the ongoing investigation and anticipated filing of criminal and/or civil actions. At a minimum, the request must include the following:

(A) Identification of the entity under suspension.

(B) The amount of time needed for continued suspension in order to implement the criminal and/or civil proceedings.

(C) A statement of why and/or how criminal and/or civil actions may be affected if the requested extension is not granted.

(e) *Disposition of suspended payments.* Payments suspended under the authority of §405.371(b) are first applied to reduce or eliminate any overpayments determined by the intermediary, carrier, or CMS, including any interest assessed under the provisions of §405.378, and then applied to reduce any other obligation to CMS or to HHS. In the absence of a legal requirement that the excess be paid to another entity, the excess is released to the provider or supplier.

[61 FR 63746, Dec. 2, 1996]

§405.373 Proceeding for offset or recoupment.

(a) *General rule.* Except as specified in paragraph (b) of this section, if the intermediary, carrier, or CMS has determined that an offset or recoupment of payments under §405.371(a)(2) should be put into effect, the intermediary or carrier must—

(1) Notify the provider or supplier of its intention to offset or recoup payment, in whole or in part, and the reasons for making the offset or recoupment; and

(2) Give the provider or supplier an opportunity for rebuttal in accordance with §405.374.

(b) Paragraph (a) of this section does not apply if the intermediary, after furnishing a provider a written notice of the amount of program reimbursement in accordance with §405.1803, recoups payment under paragraph (c) of §405.1803. (For provider rights in this circumstance, see §§405.1809, 405.1811, 405.1815, 405.1835, and 405.1843.)

(c) *Actions following receipt of rebuttal statement.* If a provider or supplier submits, in accordance with §405.374, a statement as to why an offset or recoupment should not be put into effect on the date specified in the notice, the intermediary or carrier must comply with the time limits and notification requirements of §405.375.

(d) *No rebuttal statement received.* If, by the end of the time period specified in the notice, no statement has been received, the recoupment or offset goes into effect automatically.

(e) *Duration of recoupment or offset.* If a recoupment or offset is put into effect, it remains in effect until the earliest of the following:

(1) The overpayment and any assessed interest are liquidated.

(2) The intermediary or carrier obtains a satisfactory agreement from the provider or supplier for liquidation of the overpayment.

(3) The intermediary or carrier, on the basis of subsequently acquired evidence or otherwise, determines that there is no overpayment.

[61 FR 63747, Dec. 2, 1996]

§405.374 Opportunity for rebuttal.

(a) *General rule.* If prior notice of the suspension of payment, offset, or recoupment is given under §405.372 or §405.373, the intermediary or carrier must give the provider or supplier an opportunity, before the suspension, offset, or recoupment takes effect, to submit any statement (to include any pertinent information) as to why it should not be put into effect on the date specified in the notice. Except as provided in paragraph (b) of this section, the provider or supplier has at least 15 days following the date of notification to submit the statement.

(b) *Exception.* The intermediary or carrier may for cause—

(1) Impose a shorter period for rebuttal; or

(2) Extend the time within which the statement must be submitted.

[61 FR 63747, Dec. 2, 1996]

§ 405.375 Time limits for, and notification of, administrative determination after receipt of rebuttal statement.

(a) *Submission and disposition of evidence.* If the provider or supplier submits a statement, under § 405.374, as to why a suspension of payment, offset, or recoupment should not be put into effect, or, under § 405.372(b)(2), why a suspension should be terminated, CMS, the intermediary, or carrier must within 15 days, from the date the statement is received, consider the statement (including any pertinent evidence submitted), together with any other material bearing upon the case, and determine whether the facts justify the suspension, offset, or recoupment or, if already initiated, justify the termination of the suspension, offset, or recoupment. Suspension, offset, or recoupment is not delayed beyond the date stated in the notice in order to review the statement.

(b) *Notification of determination.* The intermediary or carrier must send written notice of the determination made under paragraph (a) of this section to the provider or supplier. The notice must—

(1) In the case of offset or recoupment, contain rationale for the determination; and

(2) In the case of suspension of payment, contain specific findings on the conditions upon which the suspension is initiated, continued, or removed and an explanatory statement of the determination.

(c) *Determination is not appealable.* A determination made under paragraph (a) of this section is not an initial determination and is not appealable.

[61 FR 63747, Dec. 2, 1996]

§ 405.376 Suspension and termination of collection action and compromise of claims for overpayment.

(a) *Basis and purpose.* This section contains requirements and procedures for the compromise of, or suspension or termination of collection action on, claims for overpayments against a provider or a supplier under the Medicare program. It is adopted under the authority of the Federal Claims Collection Act (31 U.S.C. 3711). Collection and compromise of claims against Medicare beneficiaries are explained at 20 CFR 404.515.

(b) *Definitions.* As used in this section, *debtor* means a provider of services or a physician or other supplier of services that has been overpaid under title XVIII of the Social Security Act. It includes an individual, partnership, corporation, estate, trust, or other legal entity.

(c) *Basic conditions.* A claim for recovery of Medicare overpayments against a debtor may be compromised, or collection action on it may be suspended or terminated, by the Centers for Medicare & Medicaid Services (CMS) if;

(1) The claim does not exceed $100,000, or such higher amount as the Attorney General may from time to time prescribe, exclusive of interest; and

(2) There is no indication of fraud, the filing of a false claim, or misrepresentation on the part of the debtor or any director, partner, manager, or other party having an interest in the claim.

(d) *Basis for compromise.* A claim may be compromised for one or more of the following reasons:

(1) The debtor, or the estate of a deceased debtor, does not have the present or prospective ability to pay the full amount within a reasonable time;

(2) The debtor refuses to pay the claim in full and the United States is unable to collect the full amount within a reasonable time by legal proceedings;

(3) There is real doubt the United States can prove its case in court; or

(4) The cost of collecting the claim does not justify enforced collection of the full amount.

(e) *Basis for termination of collection action.* Collection action may be terminated for one or more of the following reasons:

(1) The United States cannot enforce collection of any significant sum;

(2) The debtor cannot be located, there is no security to be liquidated, the statute of limitations has run, and the prospects of collecting by offset are

too remote to justify retention of the claim;

(3) The cost of further collection action is likely to exceed any recovery;

(4) It is determined the claim is without merit; or

(5) Evidence to substantiate the claim is no longer available.

(f) *Basis for suspension of collection action.* Collection action may be suspended for either of the following reasons if future collection action is justified based on potential productivity, including foreseeable ability to pay, and size of claim:

(1) The debtor cannot be located; or

(2) The debtor is unable to make payments on the claim or to fulfill an acceptable compromise.

(g) *Factors considered.* In determining whether a claim will be compromised, or collection action terminated or suspended, CMS will consider the following factors:

(1) Age and health of the debtor, present and potential income, inheritance prospects, possible concealment or fraudulent transfer of assets, and the availability of assets which may be reached by enforced collection proceedings, for compromise under paragraph (d)(1) of this section, termination under paragraph (e)(1) of this section, and suspension under paragraph (f)(2) of this section;

(2) Applicable exemptions available to a debtor and uncertainty concerning the price of the property in a forced sale, for compromise under paragraph (d)(2) of this section and termination under paragraph (e)(1) of this section; and

(3) The probability of proving the claim in court, the probability of full or partial recovery, the availability of necessary evidence, and related pragmatic considerations, for compromise under paragraph (d)(3) of this section.

(h) *Amount of compromise.* The amount accepted in compromise will be reasonable in relation to the amount that can be recovered by enforced collection proceedings.

Consideration shall be given to the following:

(1) The exemptions available to the debtor under State or Federal law;

(2) The time necessary to collect the overpayment;

(3) The litigative probabilities involved; and

(4) The administrative and litigative costs of collection where the cost of collecting the claim is a basis for compromise.

(i) *Payment of compromise*—(1) *Time and manner.* Payment of the amount that CMS has agreed to accept as a compromise in full settlement of a Medicare overpayment claim must be made within the time and in the manner prescribed by CMS. An overpayment claim is not compromised or settled until the full payment of the compromised amount has been made within the time and in the manner prescribed by CMS.

(2) *Failure to pay compromised amount.* Failure of the debtor or the estate to make payment as provided by the comprise reinstates the full amount of the overpayment claim, less any amounts paid prior to the default.

(j) *Effect of compromise, or suspension, or termination of collection action.* Any action taken by CMS under this section regarding the compromise of an overpayment claim, or termination or suspension of collection action on an overpayment claim, is not an initial determination for purposes of the appeal procedures under subparts G, H, and R of this part.

[43 FR 59381, Dec. 20, 1978, as amended at 57 56998, Dec. 2, 1992. Redesignated and amended at 61 FR 63745, 63747, Dec. 2, 1996]

§405.377 Withholding Medicare payments to recover Medicaid overpayments.

(a) *Basis and purpose.* This section implements section 1885 of the Act, which provides for withholding Medicare payments to certain Medicaid providers that have not arranged to repay Medicaid overpayments as determined by the Medicaid State agency or have failed to provide information necessary to determine the amount (if any) of overpayments.

(b) *When withholding may be used.* CMS may withhold Medicare payment to offset Medicaid overpayments that a Medicaid agency has been unable to collect if—

(1) The Medicaid agency has followed the procedure specified in §447.31 of this chapter; and

(2) The institution or person is one described in paragraph (c) of this section and either—

(i) Has not made arrangements satisfactory to the Medicaid agency to repay the overpayment; or

(ii) Has not provided information to the Medicaid agency necessary to enable the agency to determine the existence or amount of Medicaid overpayment.

(c) *Institutions or persons affected.* Withholding under paragraph (b) of this section may be made with respect to any of the following entities that has or had in effect an agreement with a Medicaid agency to furnish services under an approved Medicaid State plan:

(1) An institutional provider that has in effect an agreement under section 1866 of the Act. (Part 489 (Provider and Supplier Agreements) implements section 1866 of the Act.)

(2) A physician or supplier that has accepted payment on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act. (Section 424.55 sets forth the conditions a supplier agrees to in accepting assignment.)

(d) *Amount to be withheld.* (1) CMS contacts the appropriate intermediary or carrier to determine the amount of Medicare payment to which the institution or person is entitled.

(2) CMS may require the intermediary or carrier to withhold Medicare payments to the institution or person by the lesser of the following amounts:

(i) The amount of the Medicare payments to which the institution or person would otherwise be entitled.

(ii) The total Medicaid overpayment to the institution or person.

(e) *Notice of withholding.* If CMS intends to withhold payments under this section, it notifies by certified mail, return receipt requested, the institution or person and the appropriate intermediary or carrier of the intention to withhold Medicare payments and follows the procedure in § 405.374. The notice includes—

(1) Identification of the institution or person; and

(2) The amount of Medicaid overpayment to be withheld from payments to which the institution or person would otherwise be entitled under Medicare.

(f) *Termination of withholding.* CMS terminates the withholding if—

(1) The Medicaid overpayment is completely recovered;

(2) The institution or person enters into an agreement satisfactory to the Medicaid agency to repay the overpayment; or

(3) The Medicaid agency determines that there is no overpayment based on newly acquired evidence or a subsequent audit.

(g) *Disposition of funds withheld.* CMS releases amounts withheld under this section to the Medicaid agency to be applied against the Medicaid overpayment made by the State agency.

[61 FR 63747, Dec. 2, 1996]

§ 405.378 Interest charges on overpayment and underpayments to providers, suppliers, and other entities.

(a) *Basis and purpose.* This section, which implements sections 1815(d) and 1833(j) of the common law and Act, and authority granted under the Federal Claims Collection Act, provides for the charging and payment of interest on overpayments and underpayments to Medicare providers, suppliers, HMOs, competitive medical plans (CMPs), and health care prepayment plans (HCPPs).

(b) *Basic rules.* (1) CMS will charge interest on overpayments, and pay interest on underpayments, to providers and suppliers of services (including physicians and other practitioners), except as specified in paragraphs (f) and (h) of this section.

(2) Interest accrues from the date of the final determination as defined in paragraph (c) of this section, and either is charged on the overpayment balance or paid on the underpayment balance for each full 30-day period that payment is delayed.

(c) *Definition of final determination.* (1) For purposes of this section, any of the following constitutes a final determination:

(i) A Notice of Amount of Program Reimbursement (NPR) is issued, as discussed in §§ 405.1803, 417.576, and 417.810, and either—

(A) A written demand for payment is made; or

(B) A written determination of an underpayment is made by the intermediary after a cost report is filed.

(ii) In cases in which an NPR is not used as a notice of determination (that is, primarily under part B), one of the following determinations is issued—

(A) A written determination that an overpayment exists and a written demand for payment;

(B) A written determination of an underpayment; or

(C) An Administrative Law Judge (ALJ) decision that reduces the amount of an overpayment below the amount that CMS has already collected.

(iii) Other examples of cases in which an NPR is not used are carrier reasonable charge determinations under subpart E of this part, interim cost settlements made for HMOs, CMPs, and HCPPs under §§417.574 and 417.810(e) of this chapter, and initial retroactive adjustment determinations under §413.64(f)(2) of this chapter. In the case of interim cost settlements and initial retroactive adjustment determinations, if the debtor does not dispute the adjustment determination within the timeframe designated in the notice of the determination (generally at least 15 days), a final determination is deemed to have been made. If the provider or supplier does dispute portions of the determination, a final determination is deemed to have been made on those portions when the intermediary issues a new determination in response to the dispute.

(iv) The due date of a timely-filed cost report that indicates an amount is due CMS, and is not accompanied by payment in full. (If an additional overpayment or underpayment is determined by the carrier or intermediary, a final determination on the additional amount is made in accordance with paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii), of this section.)

(v) With respect to a cost report that is not filed on time, the day following the date the cost report was due (plus a single extension of time not to exceed 30 days if granted for good cause), until the time as a cost report is filed. (When the cost report is subsequently filed, there is an additional determination as specified in paragraphs (c)(1) (i), (ii), (iii), or (iv) of this section.)

(2) Except as required by any subsequent administrative or judicial reversal, interest accrues from the date of final determination as specified in this subsection.

(d) *Rate of interest.* (1) The interest rate on overpayments and underpayments is the higher of—

(i) The rate as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of final determination as defined in paragraph (c) of this section (this rate is published quarterly in the FEDERAL REGISTER by the Department under 45 CFR 30.13(a)); or

(ii) The current value of funds rate (this rate is published annually in the FEDERAL REGISTER by the Secretary of the Treasury, subject to quarterly revisions).

(2) [Reserved]

(e) *Accrual of interest.* (1) If a cost report is filed that does not indicate an amount is due CMS but the intermediary makes a final determination that an overpayment exists, or if a carrier makes a final determination that an overpayment to a physician or supplier exists, interest will accrue beginning with the date of such final determination. Interest will continue to accrue during periods of administrative and judicial appeal and until final disposition of the claim.

(2)(i) If a cost report is filed and indicates that an amount is due CMS, interest on the amount due will accrue from the due date of the cost report unless—

(A) Full payment on the amount due accompanies the cost report; or

(B) The provider and the intermediary agree in advance to liquidate the overpayment through a reduction in interim payments over the next 30-day period.

(ii) If the intermediary determines an additional overpayment during the cost settlement process, interest will accrue from the date of each determination.

(iii) The interest rate on each of the final determinations of an overpayment will be the rate of interest in effect on the date the determination is made.

(3) In the case of a cost report that is not filed on time, interest also will accrue on a determined overpayment

from the day following the due date of the report (plus a single extension of time not to exceed 30 days if granted for good cause, as specified in §413.24(f)) of this chapter, to the time the cost report is filed.

(4) If an intermediary or a carrier makes a final determination that an underpayment exists, interest to the provider or the supplier will accrue from the date of notification of the underpayment.

(f) *Waiver of interest charges.* (1) When an intermediary or a carrier makes a final determination that an overpayment or underpayment exists, as specified in paragraphs (e)(1), (e)(2)(ii), and (e)(4)—

(i) Interest charges will be waived if the overpayment or underpayment is completely liquidated within 30 days from the date of the final determination.

(ii) CMS may waive interest charges if it determines that the administrative cost of collecting them exceeds the interest charges.

(2) Interest will not be waived for that period of time during which the cost report was due but remained unfiled for more than 30 days, as specified in paragraph (e)(3) of this section.

(g) *Rules applicable to partial payments.* If an overpayment is repaid in installments or recouped by withholding from several payments due the provider or supplier of services—

(1) Each payment or recoupment will be applied first to accrued interest and then to the principal; and

(2) After each payment or recoupment, interest will accrue on the remaining unpaid balance.

(h) *Exceptions to applicability.* (1) The provisions of this section do not apply to the time period for which interest is payable under §413.64(j) of this chapter because the provider seeks judicial review of a decision of the Provider Reimbursement Review Board, or a subsequent reversal, affirmance, or modification of that decision by the Administrator. Prior to that time, until the provider seeks judicial review, interest accrues at the rate specified in this section on outstanding unpaid balances resulting from final determinations as defined in paragraph (c) of this section.

(2) If an overpayment or an underpayment determination is reversed administratively or judicially, and the reversal is no longer subject to appeal, appropriate adjustments will be made with respect to the overpayment or underpayment and the amount of interest charged.

(i) *Nonallowable cost.* As specified in §§412.113 and 413.153 of this chapter, interest accrued on overpayments and interest on funds borrowed specifically to repay overpayments are not considered allowable costs, up to the amount of the overpayment, unless the provider had made a prior commitment to borrow funds for other purposes (for example, capital improvements).

(See §413.153(a)(2) of this chapter for exceptions based on administrative or judicial reversal.)

[47 FR 54814, Dec. 6, 1982, as amended at 49 FR 36102, Sept. 14, 1984; 49 FR 44472, Nov. 7, 1984; 51 FR 34792, Sept. 30, 1986; 56 FR 31336, July 10, 1991. Redesignated at 61 FR 63745, Dec. 2, 1996; 69 FR 45607, July 30, 2004]

REPAYMENT OF SCHOLARSHIPS AND LOANS

§ 405.380 Collection of past-due amounts on scholarship and loan programs.

(a) *Basis and purpose.* This section implements section 1892 of the Act, which authorizes the Secretary to deduct from Medicare payments for services amounts considered as past-due obligations under the National Health Service Corps Scholarship program, the Physician Shortage Area Scholarship program, and the Health Education Assistance Loan program.

(b) *Offsetting against Medicare payment.* (1) Medicare carriers and intermediaries offset against Medicare payments in accordance with the signed repayment agreement between the Public Health Service and individuals who have breached their scholarship or loan obligations and who—

(i) Accept Medicare assignment for services;

(ii) Are employed by or affiliated with a provider, HMO, or Competitive Medical Plan (CMP) that receives Medicare payment for services; or

(iii) Are members of a group practice that receives Medicare payment for services.

(2) For purposes of this section, ''provider'' includes all entities eligible to receive Medicare payment in accordance with an agreement under section 1866 of the Act.

(c) *Beginning of offset.* (1) The Medicare carrier offsets Medicare payments beginning six months after it notifies the individual or the group practice of the amount to be deducted and the particular individual to whom the deductions are attributable.

(2) The Medicare intermediary offsets payments beginning six months after it notifies the provider, HMO, CMP or group practice of the amount to be deducted and the particular individuals to whom the deductions are attributable. Offset of payments is made in accordance with the terms of the repayment agreement. If the individual ceases to be employed by the provider, HMO, or CMP, or leaves the group practice, no deduction is made.

(d) *Refusal to offset against Medicare payment.* If the individual refuses to enter into a repayment agreement, or breaches any provision of the agreement, or if Medicare payment is insufficient to maintain the offset collection according to the agreed upon formula, then—

(1) The Department, within 30 days if feasible, informs the Attorney General; and

(2) The Department excludes the individual from Medicare until the entire past due obligation has been repaid, unless the individual is a sole community practitioner or the sole source of essential specialized services in a community and the State requests that the individual not be excluded.

[57 FR 19092, May 4, 1992]

Subpart D—Private Contracts

AUTHORITY: Secs. 1102, 1802, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395a, and 1395hh).

SOURCE: 63 FR 58901, Nov. 2, 1998, unless otherwise noted.

§405.400 Definitions.

For purposes of this subpart, the following definitions apply:

Beneficiary means an individual who is enrolled in Part B of Medicare.

Emergency care services means services furnished to an individual for treatment of an ''emergency medical condition'' as that term is defined in §422.2 of this chapter.

Legal representative means one or more individuals who, as determined by applicable State law, has the legal authority to enter into the contract with the physician or practitioner on behalf of the beneficiary.

Opt-out means the status of meeting the conditions specified in §405.410.

Opt-out period means the 2-year period beginning on the effective date of the affidavit as specified by §405.410(c)(1) or §405.410(c)(2), as applicable.

Participating physician means a ''physician'' as defined in this section who has signed an agreement to participate in Part B of Medicare.

Physician means a doctor of medicine; doctor of osteopathy; doctor of dental surgery or of dental medicine; doctor of podiatric medicine; or doctor of optometry who is legally authorized to practice medicine, osteopathy, dental surgery, dental medicine, podiatric medicine, or optometry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions.

Practitioner means a physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, clinical psychologist, clinical social worker, registered dietitian or nutrition professional, who is currently legally authorized to practice in that capacity by each State in which he or she furnishes services to patients or clients.

Private contract means a document that meets the criteria specified in §405.415.

Properly opt-out means to complete, without defect, the requirements for opt-out as specified in §405.410.

Properly terminate opt-out means to complete, without defect, the requirements for terminating opt-out as specified in §405.445.

Urgent care services means services furnished to an individual who requires services to be furnished within 12 hours in order to avoid the likely onset of an emergency medical condition.

[63 FR 58901, Nov. 2, 1998, as amended at 69 FR 1116, Jan. 7, 2004; 71 FR 69782, Dec. 1, 2006]

§ 405.405 General rules.

(a) A physician or practitioner may enter into one or more private contracts with Medicare beneficiaries for the purpose of furnishing items or services that would otherwise be covered by Medicare, provided the conditions of this subpart are met.

(b) A physician or practitioner who enters into at least one private contract with a Medicare beneficiary under the conditions of this subpart, and who submits one or more affidavits in accordance with this subpart, opts-out of Medicare for a 2-year period unless the opt-out is terminated early according to §405.445. The physician's or practitioner's opt-out may be renewed for subsequent 2-year periods.

(c) Both the private contracts described in paragraph (a) of this section and the physician's or practitioner's opt-out described in paragraph (b) of this section are null and void if the physician or practitioner fails to properly opt-out in accordance with the conditions of this subpart.

(d) Both the private contracts described in paragraph (a) of this section and the physician's or practitioner's opt-out described in paragraph (b) of this section are null and void for the remainder of the opt-out period if the physician or practitioner fails to remain in compliance with the conditions of this subpart during the opt-out period.

(e) Services furnished under private contracts meeting the requirements of this subpart are not covered services under Medicare, and no Medicare payment will be made for such services either directly or indirectly, except as permitted in accordance with §405.435(c).

§ 405.410 Conditions for properly opting-out of Medicare.

The following conditions must be met for a physician or practitioner to properly opt-out of Medicare:

(a) Each private contract between a physician or a practitioner and a Medicare beneficiary that is entered into prior to the submission of the affidavit described in paragraph (b) of this section must meet the specifications of §405.415.

(b) The physician or practitioner must submit an affidavit that meets the specifications of §405.420 to each Medicare carrier with which he or she would file claims absent completion of opt-out.

(c) A nonparticipating physician or a practitioner may opt-out of Medicare at any time in accordance with the following:

(1) The 2-year opt-out period begins the date the affidavit meeting the requirements of §405.420 is signed, provided the affidavit is filed within 10 days after he or she signs his or her first private contract with a Medicare beneficiary.

(2) If the physician or practitioner does not timely file any required affidavit, the 2-year opt-out period begins when the last such affidavit is filed. Any private contract entered into before the last required affidavit is filed becomes effective upon the filing of the last required affidavit and the furnishing of any items or services to a Medicare beneficiary under such contract before the last required affidavit is filed is subject to standard Medicare rules.

(d) A participating physician may properly opt-out of Medicare at the beginning of any calendar quarter, provided that the affidavit described in §405.420 is submitted to the participating physician's Medicare carriers at least 30 days before the beginning of the selected calendar quarter. A private contract entered into before the beginning of the selected calendar quarter becomes effective at the beginning of the selected calendar quarter and the furnishing of any items or services to a Medicare beneficiary under such contract before the beginning of the selected calendar quarter is subject to standard Medicare rules.

§ 405.415 Requirements of the private contract.

A private contract under this subpart must:

(a) Be in writing and in print sufficiently large to ensure that the beneficiary is able to read the contract.

(b) Clearly state whether the physician or practitioner is excluded from Medicare under sections 1128, 1156, or 1892 or any other section of the Social Security Act.

(c) State that the beneficiary or his or her legal representative accepts full responsibility for payment of the physician's or practitioner's charge for all services furnished by the physician or practitioner.

(d) State that the beneficiary or his or her legal representative understands that Medicare limits do not apply to what the physician or practitioner may charge for items or services furnished by the physician or practitioner.

(e) State that the beneficiary or his or her legal representative agrees not to submit a claim to Medicare or to ask the physician or practitioner to submit a claim to Medicare.

(f) State that the beneficiary or his or her legal representative understands that Medicare payment will not be made for any items or services furnished by the physician or practitioner that would have otherwise been covered by Medicare if there was no private contract and a proper Medicare claim had been submitted.

(g) State that the beneficiary or his or her legal representative enters into this contract with the knowledge that he or she has the right to obtain Medicare-covered items and services from physicians and practitioners who have not opted-out of Medicare, and that the beneficiary is not compelled to enter into private contracts that apply to other Medicare-covered services furnished by other physicians or practitioners who have not opted-out.

(h) State the expected or known effective date and expected or known expiration date of the opt-out period.

(i) State that the beneficiary or his or her legal representative understands that Medigap plans do not, and that other supplemental plans may elect not to, make payments for items and services not paid for by Medicare.

(j) Be signed by the beneficiary or his or her legal representative and by the physician or practitioner.

(k) Not be entered into by the beneficiary or by the beneficiary's legal representative during a time when the beneficiary requires emergency care services or urgent care services. (However, a physician or practitioner may furnish emergency or urgent care services to a Medicare beneficiary in accordance with § 405.440.)

(l) Be provided (a photocopy is permissible) to the beneficiary or to his or her legal representative before items or services are furnished to the beneficiary under the terms of the contract.

(m) Be retained (original signatures of both parties required) by the physician or practitioner for the duration of the opt-out period.

(n) Be made available to CMS upon request.

(o) Be entered into for each opt-out period.

§ 405.420 Requirements of the opt-out affidavit.

An affidavit under this subpart must:

(a) Be in writing and be signed by the physician or practitioner.

(b) Contain the physician's or practitioner's full name, address, telephone number, national provider identifier (NPI) or billing number, if one has been assigned, uniform provider identification number (UPIN) if one has been assigned, or, if neither an NPI nor a UPIN has been assigned, the physician's or practitioner's tax identification number (TIN).

(c) State that, except for emergency or urgent care services (as specified in § 405.440), during the opt-out period the physician or practitioner will provide services to Medicare beneficiaries only through private contracts that meet the criteria of paragraph § 405.415 for services that, but for their provision under a private contract, would have been Medicare-covered services.

(d) State that the physician or practitioner will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will the physician or practitioner permit any entity acting on his or her behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary, except as specified in § 405.440.

(e) State that, during the opt-out period, the physician or practitioner understands that he or she may receive no direct or indirect Medicare payment for services that he or she furnishes to Medicare beneficiaries with whom he or she has privately contracted, whether as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under a Medicare+Choice plan.

(f) State that a physician or practitioner who opts-out of Medicare acknowledges that, during the opt-out period, his or her services are not covered under Medicare and that no Medicare payment may be made to any entity for his or her services, directly or on a capitated basis.

(g) State a promise by the physician or practitioner to the effect that, during the opt-out period, the physician or practitioner agrees to be bound by the terms of both the affidavit and the private contracts that he or she has entered into.

(h) Acknowledge that the physician or practitioner recognizes that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by the physician or practitioner during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom he or she has not previously privately contracted) without regard to any payment arrangements the physician or practitioner may make.

(i) With respect to a physician who has signed a Part B participation agreement, acknowledge that such agreement terminates on the effective date of the affidavit.

(j) Acknowledge that the physician or practitioner understands that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services and that the rules of § 405.440 apply if the physician furnishes such services.

§ 405.425 Effects of opting-out of Medicare.

If a physician or practitioner opts-out of Medicare in accordance with this subpart for the 2-year period for which the opt-out is effective, the following results obtain:

(a) Except as provided in § 405.440, no payment may be made directly by Medicare or by any Medicare+Choice plan to the physician or practitioner or to any entity to which the physician or practitioner reassigns his right to receive payment for services.

(b) The physician or practitioner may not furnish any item or service that would otherwise be covered by Medicare (except for emergency or urgent care services) to any Medicare beneficiary except through a private contract that meets the requirements of this subpart.

(c) The physician or practitioner is not subject to the requirement to submit a claim for items or services furnished to a Medicare beneficiary, as specified in § 424.5(a)(6) of this chapter, except as provided in § 405.440.

(d) The physician or practitioner is prohibited from submitting a claim to Medicare for items or services furnished to a Medicare beneficiary except as provided in § 405.440.

(e) In the case of a physician, he or she is not subject to the limiting charge provisions of § 414.48 of this chapter, except for services provided under § 405.440.

(f) The physician or practitioner is not subject to the prohibition-on-reassignment provisions of § 414.80 of this chapter, except for services provided under § 405.440.

(g) In the case of a practitioner, he or she is not prohibited from billing or collecting amounts from beneficiaries (as provided in 42 U.S.C. 1395u(b)(18)(B)).

(h) The death of a beneficiary who has entered into a private contract (or whose legal representative has done so) does not invoke § 424.62 or § 424.64 of this chapter with respect to the physician or practitioner with whom the beneficiary (or legal representative) has privately contracted.

(i) The physician or practitioner who has not been excluded under sections 1128, 1156, or 1892 of the Social Security

Act may order, certify the need for, or refer a beneficiary for Medicare-covered items and services, provided the physician or practitioner is not paid, directly or indirectly, for such services (except as provided in §405.440).

(j) The physician or practitioner who is excluded under sections 1128, 1156, or 1892 of the Social Security Act may not order, prescribe, or certify the need for Medicare-covered items and services except as provided in §1001.1901 of this title, and must otherwise comply with the terms of the exclusion in accordance with §1001.1901 effective with the date of the exclusion.

§405.430 Failure to properly opt-out.

(a) A physician or practitioner fails to properly opt-out if—

(1) Any private contract between the physician or practitioner and a Medicare beneficiary, that was entered into before the affidavit described in §405.420 was filed, does not meet the specifications of §405.415; or

(2) He or she fails to submit the affidavit(s) in accordance with §405.420.

(b) If a physician or practitioner fails to properly opt-out in accordance with paragraph (a) of this section, the following results obtain:

(1) The physician's or practitioner's attempt to opt-out of Medicare is nullified, and all of the private contracts between the physician or practitioner and Medicare beneficiaries for the two-year period covered by the attempted opt-out are deemed null and void.

(2) The physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries, including the items and services furnished under the nullified contracts. A nonparticipating physician is subject to the limiting charge provisions of §414.48 of this chapter. A participating physician is subject to the limitations on charges of the participation agreement he or she signed.

(3) The practitioner may not reassign any claim except as provided in §424.80 of this chapter.

(4) The practitioner may neither bill nor collect an amount from the beneficiary except for applicable deductible and coinsurance amounts.

(5) The physician or practitioner may make another attempt to properly opt-out at any time.

§405.435 Failure to maintain opt-out.

(a) A physician or practitioner fails to maintain opt-out under this subpart if, during the opt-out period—

(1) He or she knowingly and willfully—

(i) Submits a claim for Medicare payment (except as provided in §405.440); or

(ii) Receives Medicare payment directly or indirectly for Medicare-covered services furnished to a Medicare beneficiary (except as provided in §405.440).

(2) He or she fails to enter into private contracts with Medicare beneficiaries for the purpose of furnishing items and services that would otherwise be covered by Medicare, or enters into contracts that fail to meet the specifications of §405.415; or

(3) He or she fails to comply with the provisions of §405.440 regarding billing for emergency care services or urgent care services; or

(4) He or she fails to retain a copy of each private contract that he or she has entered into for the duration of the opt-out period for which the contracts are applicable or fails to permit CMS to inspect them upon request.

(b) If a physician or practitioner fails to maintain opt-out in accordance with paragraph (a) of this section, then, for the remainder of the opt-out period, except as provided by paragraph (d) of this section—

(1) All of the private contracts between the physician or practitioner and Medicare beneficiaries are deemed null and void.

(2) The physician's or practitioner's opt-out of Medicare is nullified.

(3) The physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries.

(4) The physician or practitioner or beneficiary will not receive Medicare payment on Medicare claims for the remainder of the opt-out period, except as provided in paragraph (c) of this section.

(5) The physician is subject to the limiting charge provisions of § 414.48 of this chapter.

(6) The practitioner may not reassign any claim except as provided in § 424.80 of this chapter.

(7) The practitioner may neither bill nor collect any amount from the beneficiary except for applicable deductible and coinsurance amounts.

(8) The physician or practitioner may not attempt to once more meet the criteria for properly opting-out until the 2-year opt-out period expires.

(c) Medicare payment may be made for the claims submitted by a beneficiary for the services of an opt-out physician or practitioner when the physician or practitioner did not privately contract with the beneficiary for services that were not emergency care services or urgent care services and that were furnished no later than 15 days after the date of a notice by the carrier that the physician or practitioner has opted-out of Medicare.

(d) If a physician or practitioner demonstrates that he or she has taken good faith efforts to maintain opt-out (including by refunding amounts in excess of the charge limits to beneficiaries with whom he or she did not sign a private contract) within 45 days of a notice from the carrier of a violation of paragraph (a) of this section, then the requirements of paragraphs (b)(1) through (b)(8) of this section are not applicable. In situations where a violation of paragraph (a) of this section is not discovered by the carrier during the 2-year opt-out period when the violation actually occurred, then the requirements of paragraphs (b)(1) through (b)(8) of this section are applicable from the date that the first violation of paragraph (a) of this section occurred until the end of the opt-out period during which the violation occurred (unless the physician or practitioner takes good faith efforts, within 45 days of any notice from the carrier that the physician or practitioner failed to maintain opt-out, or within 45 days of the physician's or practitioner's discovery of the failure to maintain opt-out, whichever is earlier, to correct his or her violations of paragraph (a) of this section. Good faith efforts include, but are not limited to, refunding any amounts collected in excess of the charge limits to beneficiaries with whom he or she did not sign a private contract.

[63 FR 58901, Nov. 2, 1998, as amended at 70 FR 70329, Nov. 21, 2005]

§ 405.440 Emergency and urgent care services.

(a) A physician or practitioner who has opted-out of Medicare under this subpart need not enter into a private contract to furnish emergency care services or urgent care services to a Medicare beneficiary. Accordingly, a physician or practitioner will not be determined to have failed to maintain opt-out if he or she furnishes emergency care services or urgent care services to a Medicare beneficiary with whom the physician or practitioner has not previously entered into a private contract, provided the physician or practitioner complies with the billing requirements specified in paragraph (b) of this section.

(b) When a physician or practitioner who has not been excluded under sections 1128, 1156, or 1892 of the Social Security Act furnishes emergency care services or urgent care services to a Medicare beneficiary with whom the physician or practitioner has not previously entered into a private contract, he or she:

(1) Must submit a claim to Medicare in accordance with both 42 CFR part 424 and Medicare instructions (including but not limited to complying with proper coding of emergency or urgent care services furnished by physicians and practitioners who have opted-out of Medicare).

(2) May collect no more than—

(i) The Medicare limiting charge, in the case of a physician; or

(ii) The deductible and coinsurance, in the case of a practitioner.

(c) Emergency care services or urgent care services furnished to a Medicare beneficiary with whom the physician or practitioner has previously entered into a private contract (that is, entered into before the onset of the emergency medical condition or urgent medical condition), are furnished under the terms of the private contract.

(d) Medicare may make payment for emergency care services or urgent care

services furnished by a physician or practitioner who has properly opted-out when the services are furnished and the claim for services is made in accordance with this section. A physician or practitioner who has been excluded must comply with the regulations at § 1001.1901 (Scope and effect of exclusion) of this title when he or she furnishes emergency services to beneficiaries and may not bill and be paid for urgent care services.

§ 405.445 Renewal and early termination of opt-out.

(a) A physician or practitioner may renew opt-out by filing an affidavit with each carrier with which he or she would file claims absent completion of opt-out, provided the affidavits are filed within 30 days after the current opt-out period expires.

(b) To properly terminate opt-out a physician or practitioner must:

(1) Not have previously opted out of Medicare.

(2) Notify all Medicare carriers, with which he or she filed an affidavit, of the termination of the opt-out no later than 90 days after the effective date of the opt-out period.

(3) Refund to each beneficiary with whom he or she has privately contracted all payment collected in excess of:

(i) The Medicare limiting charge (in the case of physicians); or

(ii) The deductible and coinsurance (in the case of practitioners).

(4) Notify all beneficiaries with whom the physician or practitioner entered into private contracts of the physician's or practitioner's decision to terminate opt-out and of the beneficiaries' right to have claims filed on their behalf with Medicare for the services furnished during the period between the effective date of the opt-out and the effective date of the termination of the opt-out period.

(c) When the physician or practitioner properly terminates opt-out in accordance with paragraph (b), he or she will be reinstated in Medicare as if there had been no opt-out, and the provision of § 405.425 shall not apply unless the physician or practitioner subsequently properly opts out.

(d) A physician or practitioner who has completed opt-out on or before January 1, 1999 may terminate opt-out during the 90 days following January 1, 1999 if he or she notifies all carriers to whom he or she would otherwise submit claims of the intent to terminate opt-out and complies with paragraphs (b)(3) and (4) of this section. Paragraph (c) of this section applies in these cases.

§ 405.450 Appeals.

(a) A determination by CMS that a physician or practitioner has failed to properly opt-out, failed to maintain opt-out, failed to timely renew opt-out, failed to privately contract, or failed to properly terminate opt-out is an initial determination for purposes of § 405.803.

(b) A determination by CMS that no payment can be made to a beneficiary for the services of a physician who has opted-out is an initial determination for purposes of § 405.803.

§ 405.455 Application to Medicare+Choice contracts.

An organization that has a contract with CMS to provide one or more Medicare+Choice (M+C) plans to beneficiaries (part 422 of this chapter):

(a) Must acquire and maintain information from Medicare carriers on physicians and practitioners who have opted-out of Medicare.

(b) Must make no payment directly or indirectly for Medicare covered services furnished to a Medicare beneficiary by a physician or practitioner who has opted-out of Medicare.

(c) May make payment to a physician or practitioner who furnishes emergency or urgent care services to a beneficiary who has not previously entered into a private contract with the physician or practitioner in accordance with § 405.440.

Subpart E—Criteria for Determining Reasonable Charges

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 32 FR 12599, Aug. 31, 1967, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.500 Basis.

Subpart E is based on the provisions of the following sections of the Act: Section 1814(b) provides for Part A payment on the basis of the lesser of a provider's reasonable costs or customary charges. Section 1832 establishes the scope of benefits provided under the Part B supplementary medical insurance program. Section 1833(a) sets forth the amounts of payment for supplementary medical insurance services on the basis of the lesser of a provider's reasonable costs or customary charges. Section 1834(a) specifies how payments are made for the purchase or rental of new and used durable medical equipment for Medicare beneficiaries. Section 1834(b) provides for payment for radiologist services on a fee schedule basis. Section 1834(c) provides for payments and standards for screening mammography. Section 1842(b) sets forth the provisions for a carrier to enter into a contract with the Secretary and to make determinations with respect to Part B claims. Section 1842(h) sets forth the requirements for a physician or supplier to voluntarily enter into an agreement with the Secretary to become a participating physician or supplier. Section 1842(i) sets forth the provisions for the payment of Part B claims. Section 1848 establishes a fee schedule for payment of physician services. Section 1861(b) sets forth the inpatient hospital services covered by the Medicare program. Section 1861(s) sets forth medical and other health services covered by the Medicare program. Section 1861(v) sets forth the general authority under which CMS may establish limits on provider costs recognized as reasonable in determining Medicare program payments. Section 1861(aa) sets forth the rural health clinic services and Federally qualified health center services covered by the Medicare program. Section 1861(jj) defines the term ''covered osteoporosis drug.'' Section 1862(a)(14) lists services that are excluded from coverage. Section 1866(a) specifies the terms for provider agreements. Section 1881 authorizes special rules for the coverage of and payment for services furnished to patients with end-stage renal disease. Section 1886 sets forth the requirements for payment to hospitals for inpatient hospital services. Section 1887 sets forth requirements for payment of provider-based physicians and payment under certain percentage arrangements. Section 1889 provides for Medicare and Medigap information by telephone.

[60 FR 63175, Dec. 8, 1995]

§ 405.501 Determination of reasonable charges.

(a) Except as specified in paragraphs (b), (c), and (d) of this section, Medicare pays no more for Part B medical and other health services than the ''reasonable charge'' for such service. The reasonable charge is determined by the carriers (subject to any deductible and coinsurance amounts as specified in §§ 410.152 and 410.160 of this chapter).

(b) Part B of Medicare pays on the basis of ''reasonable cost'' (see part 413 of this chapter) for certain institutional services, certain services furnished under arrangements with institutions, and services furnished by entities that elect to be paid on a cost basis (including health maintenance organizations, rural health clinics, Federally qualified health centers and end-stage renal disease facilities).

(c) Carriers will determine the reasonable charge on the basis of the criteria specified in § 405.502, and the customary and prevailing charge screens in effect when the service was furnished. (Also see §§ 415.55 through 415.70 and §§ 415.100 through 415.130 of this chapter, which pertain to the determination of reimbursement for services performed by hospital-based physicians.) However, when services are furnished more than 12 months before the beginning of the fee screen year (January 1 through December 30) in which a request for payment is made, payment is based on the customary and prevailing charge screens in effect for the fee screen year that ends immediately preceding the fee screen year in which the claim or request for payment is made.

(d) Payment under Medicare Part B for durable medical equipment and

prosthetic and orthotic devices is determined in accordance with the provisions of subpart D of part 414 of this chapter.

[47 FR 63274, Dec. 31, 1981, as amended at 51 FR 34978, Oct. 1, 1986; 51 FR 37911, Oct. 27, 1986; 54 FR 9003, Mar. 2, 1989; 57 FR 24975, June 12, 1992; 57 FR 33896, July 31, 1992; 57 FR 57688, Dec. 7, 1992; 60 FR 63176, Dec. 8, 1995]

§405.502 Criteria for determining reasonable charges.

(a) *Criteria.* The law allows for flexibility in the determination of reasonable charges to accommodate reimbursement to the various ways in which health services are furnished and charged for. The criteria for determining what charges are reasonable include:

(1) The customary charges for similar services generally made by the physician or other person furnishing such services.

(2) The prevailing charges in the locality for similar services.

(3) In the case of physicians' services, the prevailing charges adjusted to reflect economic changes as provided under §405.504 of this subpart.

(4) In the case of medical services, supplies, and equipment that are reimbursed on a reasonable charge basis (excluding physicians' services), the inflation-indexed charge as determined under §405.509.

(5) [Reserved]

(6) In the case of medical services, supplies, and equipment (including equipment servicing) that the Secretary judges do not generally vary significantly in quality from one supplier to another, the lowest charge levels at which such services, supplies, and equipment are widely and consistently available in a locality.

(7) Other factors that may be found necessary and appropriate with respect to a category of service to use in judging whether the charge is inherently reasonable. This includes special reasonable charge limits (which may be either upper or lower limits) established by CMS or a carrier if it determines that the standard rules for calculating reasonable charges set forth in this subpart result in the grossly deficient or excessive charges. The determination of these limits is described in paragraphs (g) and (h) of this section.

(8) In the case of laboratory services billed by a physician but performed by an outside laboratory, the payment levels established in accordance with the criteria stated in §405.515.

(9) Except as provided in paragraph (a)(10) of this section, in the case of services of assistants-at-surgery as defined in §405.580 in teaching and nonteaching settings, charges that are not more than 16 percent of the prevailing charge in the locality, adjusted by the economic index, for the surgical procedure performed by the primary surgeon. Payment is prohibited for the services of an assistant-at-surgery in surgical procedures for which CMS has determined that assistants-at-surgery on average are used in less than 5 percent of such procedures nationally.

(10) In the case of services of assistants at surgery that meet the exception under §415.190(c)(2) or (c)(3) of this chapter because the physician is performing a unique, necessary, specialized medical service in the total care of a patient during surgery, reasonable charges consistent with prevailing practice in the carrier's service area rather than the special assistant at surgery rate.

(b) *Comparable services limitation.* The law also specifies that the reasonable charge cannot be higher than the charge applicable for a comparable service under comparable circumstances to the carriers' own policyholders and subscribers.

(c) *Application of criteria.* In applying these criteria, the carriers are to exercise judgment based on factual data on the charges made by physicians to patients generally and by other persons to the public in general and on special factors that may exist in individual cases so that determinations of reasonable charge are realistic and equitable.

(d) *Responsibility of Administration and carriers.* Determinations by carriers of reasonable charge are not reviewed on a case-by-case basis by the Centers for Medicare & Medicaid Services, although the general procedures and performance of functions by carriers are evaluated. In making determinations, carriers apply the provisions of the law under broad principles issued by the

Centers for Medicare & Medicaid Services. These principles are intended to assure overall consistency among carriers in their determinations of reasonable charge. The principles in §§ 405.503 through 405.507 establish the criteria for making such determinations in accordance with the statutory provisions.

(e) *Determination of reasonable charges under the End-Stage Renal Disease (ESRD) Program*—(1) *General.* Reasonable charges for renal-related items and services (furnished in connection with transplantation or dialysis) must be related to costs and allowances that are reasonable when the treatments are furnished in an effective and economical manner.

(2) *Nonprovider (independent) dialysis facilities.* Reasonable charges for renal-related items and services furnished before August 1, 1983 must be determined related to costs and charges prior to July, 1973, in accordance with the regulations at § 405.541. Items and services related to outpatient maintenance dialysis that are furnished after that date are paid for in accordance with §§ 405.544 and 413.170 of this chapter.

(3) *Provider services and (hospital-based) dialysis facilities.* Renal-related items and services furnished by providers, or by ESRD facilities based in hospitals, before August 1, 1983 are paid for under the provider reimbursement provisions found generally in part 413 of this chapter. Items and services related to outpatient maintenance dialysis that are furnished after that date are paid for in accordance with §§ 405.544 and 413.170 of this chapter.

(4) *Physicians' services.* Reasonable charges for renal-related physicians' services must be determined considering charges made for other services involving comparable physicians' time and skill requirements, in accordance with regulations at §§ 405.542 and 405.543.

(5) *Health maintenance organizations (HMOs).* For special rules concerning the reimbursement of ESRD services furnished by risk-basis HMOs, or by facilities owned or operated by or related to such HMOs by common ownership or control, see §§ 405.2042(b)(14) and 405.2050(c).

(f) *Determining payments for certain physician services furnished in outpatient hospital settings*—(1) *General rule.* If physician services of the type routinely furnished in physicians' offices are furnished in outpatient hospital settings before January 1, 1992, carriers determine the reasonable charge for those services by applying the limits described in paragraph (f)(5) of this section.

(2) *Definition.* As used in this paragraph (f), *outpatient settings* means—

(i) Hospital outpatient departments, including clinics and emergency rooms; and

(ii) Comprehensive outpatient rehabilitation facilities.

(3) *Services covered by limits.* The carrier establishes a list of services routinely furnished in physicians' offices in the area. The carrier has the discretion to determine which professional services are routinely furnished in physicians' offices, based on current medical practice in the area. Listed below are some examples of routine services furnished by office-based physicians.

Examples

Review of recent history, determination of blood pressure, ausculation of heart and lungs, and adjustment of medication.

Brief history and examination, and initiation of diagnostic and treatment programs.

Treatment of an acute respiratory infection.

(4) *Services excluded from limits.* The limits established under this paragraph do not apply to the following:

(i) Rural health clinic services.

(ii) Surgical services included on the ambulatory surgical center list of procedures published under § 416.65(c) of this chapter.

(iii) Services furnished in a hospital emergency room after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(A) Placing the patient's health in serious jeopardy;

(B) Serious impairment to bodily functions; or

(C) Serious dysfunction of any bodily organ or part.

(iv) Anesthesiology services and diagnostic and therapeutic radiology services.

(v) Federally qualified health center services paid under the rules in part 405 subpart X.

(5) *Methodology for developing limits*—(i) *Development of a charge base.* The carrier establishes a charge base for each service identified as a routine office-based physician service. The charge base consists of the prevailing charge in the locality for each such service adjusted by the economic index. The carrier uses the prevailing charges that apply to services by nonspecialists in office practices in the locality in which the outpatient setting is located.

(ii) *Calculation of the outpatient limits.* The carrier calculates the charge limit for each service by multiplying the charge base amount for each service by .60.

(6) *Application of limits.* The reasonable charge for physician services of the type described in paragraph (f)(3) of this section that are furnished in an outpatient setting is the lowest of the actual charges, the customary charges in accordance with § 405.503, the prevailing charges applicable to these services in accordance with § 405.504, or the charge limits calculated in paragraph (f)(5)(ii) of this section.

(g) *Determination of payment amounts in special circumstances.*—(1) *General.* (i) For purposes of this paragraph (g), a ''category of items or services'' may consist of a single item or service or any number of items or services.

(ii) CMS or a carrier may determine that the standard rules for calculating payment amounts set forth in this subpart for a category of items or services identified in section 1861(s) of the Act (other than physicians' services paid under section 1848 of the Act and those items and services for which payment is made under a prospective payment system, such as outpatient hospital services or home health services) will result in grossly deficient or excessive amounts. A payment amount will not be considered grossly excessive or deficient if it is determined that an overall payment adjustment of less than 15 percent is necessary to produce a realistic and equitable payment amount. For CMS-initiated adjustments, CMS will publish in the FEDERAL REGISTER an analysis of payment adjustments that exceed $100 million per year in compliance with Executive Order 12866. If CMS makes adjustments that have a significant effect on a substantial number of small entities, it will publish an analysis in compliance with the Regulatory Flexibility Act.

(iii) If CMS or the carrier determines that the standard rules for calculating payment amounts for a category of items or services will result in grossly deficient or excessive amounts, CMS, or the carrier, may establish special payment limits that are realistic and equitable for a category of items or services. If CMS makes a determination, it is considered a national determination. A carrier determination is one made by a carrier or intermediary or groups of carriers or intermediaries even if the determination applies to payment in all States.

(iv) The limit on the payment amount is either an upper limit to correct a grossly excessive payment amount or a lower limit to correct a grossly deficient payment amount.

(v) The limit is either a specific dollar amount or is based on a special method to be used in determining the payment amount.

(vi) Except as provided in paragraph (h) of this section, a payment limit for a given year may not vary by more than 15 percent from the payment amount established for the preceding year.

(vii) *Examples of excessive or deficient payment amounts.* Examples of the factors that may result in grossly deficient or excessive payment amounts include, but are not limited to, the following:

(A) The marketplace is not competitive. This includes circumstances in which the marketplace for a category of items or services is not truly competitive because a limited number of suppliers furnish the item or service.

(B) Medicare and Medicaid are the sole or primary sources of payment for a category of items or services.

(C) The payment amounts for a category of items or services do not reflect changing technology, increased facility with that technology, or

changes in acquisition, production, or supplier costs.

(D) The payment amounts for a category of items or services in a particular locality are grossly higher or lower than payment amounts in other comparable localities for the category of items or services, taking into account the relative costs of furnishing the category of items or services in the different localities.

(E) Payment amounts for a category of items or services are grossly higher or lower than acquisition or production costs for the category of items or services.

(F) There have been increases in payment amounts for a category of items or services that cannot be explained by inflation or technology.

(G) The payment amounts for a category of items or services are grossly higher or lower than the payments made for the same category of items or services by other purchasers in the same locality.

(H) A new technology exists which is not reflected in the existing payment allowances.

(2) *Establishing a limit.* In establishing a payment limit for a category of items or services, CMS or a carrier considers the available information that is relevant to the category of items or services and establishes a payment amount that is realistic and equitable. The factors CMS or a carrier considers in establishing a specific dollar amount or special payment method for a category of items or services may include, but are not limited to, the following:

(i) *Price markup.* Price markup is the relationship between the retail and wholesale prices or manufacturer's costs of a category of items or services. If information on a particular category of items or services is not available, CMS or a carrier may consider the price markup on a similar category of items or services and information on general industry pricing trends.

(ii) *Differences in charges.* CMS or a carrier may consider the differences in charges for a category of items or services made to non-Medicare and Medicare patients or to institutions and other large volume purchasers.

(iii) *Costs.* CMS or a carrier may consider resources (for example, overhead, time, acquisition costs, production costs, and complexity) required to produce a category of items or services.

(iv) *Use.* CMS or a carrier may impute a reasonable rate of use for a category of items or services and consider unit costs based on efficient use.

(v) *Payment amounts in other localities.* CMS or a carrier may consider payment amounts for a category of items or services furnished in another locality.

(3) *Notification of limits.*—(i) *National limits.* CMS publishes in the FEDERAL REGISTER proposed and final notices announcing a special payment limit described in paragraph (g) of this section before it adopts the limit. The notices set forth the criteria and circumstances, if any, under which a carrier may grant an exception to a payment limit for a category of items or services.

(ii) *Carrier-level limits.* (A) A carrier proposing to establish a special payment limit for a category of items or services must inform the affected suppliers and Medicaid agencies of the proposed payment amounts and the factors it considered in proposing the particular limit, as described in paragraphs (g)(1) through (g)(4) of this section and must solicit comments. The notice must also consider the following:

(*1*) The effects on the Medicare program, including costs, savings, assignment rates, beneficiary liability, and quality of care.

(*2*) What entities would be affected, such as classes of providers or suppliers and beneficiaries.

(*3*) How significantly would these entities be affected.

(*4*) How would the adjustment affect beneficiary access to items or services.

(B) Before publication of a final notice, the carrier must—

(*1*) Evaluate the comments it receives on the proposed notice.

(*2*) Notify CMS in writing of any final limits it plans to establish. CMS will acknowledge in writing to the carrier that it received the carrier's notification.

(*3*) After receipt of CMS' acknowledgement, inform the affected suppliers and State Medicaid agencies of any final limits it establishes.

(C) The effective date for a final payment limit may apply to services furnished at least 60 days after the date that the carrier notifies affected suppliers and State Medicaid agencies of the final limit.

(4) *Use of valid and reliable data.* In determining whether a payment amount is grossly excessive or deficient and in establishing an appropriate payment amount, valid and reliable data are used. To ensure the use of valid and reliable data, CMS or the carrier must meet the following criteria to the extent applicable:

(i) Develop written guidelines for data collection and analysis.

(ii) Ensure consistency in any survey to collect and analyze pricing data.

(iii) Develop a consistent set of survey questions to use when requesting retail prices.

(iv) Ensure that sampled prices fully represent the range of prices nationally.

(v) Consider the geographic distribution of Medicare beneficiaries.

(vi) Consider relative prices in the various localities to ensure that an appropriate mix of areas with high, medium, and low consumer prices was included.

(vii) Consider criteria to define populous State, less populous State, urban area, and rural area.

(viii) Consider a consistent approach in selecting retail outlets within selected cities.

(ix) Consider whether the distribution of sampled prices from localities surveyed is fully representative of the distribution of the U.S. population.

(x) Consider the products generally used by beneficiaries and collect prices of these products.

(xi) When using wholesale costs, consider the cost of the services necessary to furnish a product to beneficiaries.

(5) *Review of market prices.* If CMS or a carrier makes a payment adjustment of more than 15 percent under this paragraph (g), CMS or the carrier will review market prices in the years subsequent to the year that the initial reduction is effective in order to ensure that further reductions continue to be appropriate.

(h) *Special payment limit adjustments greater than 15 percent of the payment amount.* In addition to applying the general rules under paragraphs (g)(1) through (g)(5) of this section, CMS applies the following rules in establishing a payment adjustment greater than 15 percent of the payment amount for a category of items or services within a year:

(1) *Potential impact of special limit.* CMS considers the potential impact on quality, access, beneficiary liability, assignment rates, and participation of suppliers.

(2) *Supplier consultation.* Before making a determination that a payment amount for a category of items or services is not inherently reasonable by reason of its grossly excessive or deficient amount, CMS consults with representatives of the supplier industry likely to be affected by the change in the payment amount.

(3) *Publication of national limits.* If CMS determines under this paragraph (h) to establish a special payment limit for a category of items or services, it publishes in the FEDERAL REGISTER the proposed and final notices of a special payment limit before it adopts the limit. The notices set forth the criteria and circumstances, if any, under which a carrier may grant an exception to the limit for the category of items or services.

(i) *Proposed notice.* The proposed notice—

(A) Explains the factors and data that CMS considered in determining that the payment amount for a category of items or services is grossly excessive or deficient;

(B) Specifies the proposed payment amount or methodology to be established for a category of items or services;

(C) Explains the factors and data that CMS considered in determining the payment amount or methodology, including the economic justification for a uniform fee or payment limit if it is proposed;

(D) Explains the potential impacts of a limit on a category of items or services as described in paragraph (h)(1) of this section; and

(E) Allows no less than 60 days for public comment on the proposed payment limit for the category of items or services.

(ii) *Final notice.* The final notice—

(A) Explains the factors and data that CMS considered, including the economic justification for any uniform fee or payment limit established; and

(B) Responds to the public comments.

(i) *Proposed notice.* The proposed notice—

(A) Explains the factors and data that CMS considered in determining that the payment amount for a category of items or services is grossly excessive or deficient;

(B) Specifies the proposed payment amount or methodology to be established for a category of items or services;

(C) Explains the factors and data that CMS considered in determining the payment amount or methodology, including the economic justification for a uniform fee or payment limit if it is proposed;

(D) Explains the potential impacts of a limit on a category of items or services as described in paragraph (h)(1) of this section; and

(E) Allows no less than 60 days for public comment on the proposed payment limit for the category of items or services.

(ii) *Final notice.* The final notice—

(A) Explains the factors and data that CMS considered, including the economic justification for any uniform fee or payment limit established; and

(B) Responds to the public comments.

(i) *Paramedic intercept ambulance services.* (1) CMS establishes its payment allowance on a carrier-wide basis by using the median allowance from all localities within an individual carrier's jurisdiction.

(2) CMS's payment allowance is equal to the advanced life support rate minus 40 percent of the basic life support rate.

(3) CMS bases payment on the lower of the actual charge or the amount described in paragraph (i)(1) and (i)(2) of this section.

(Secs. 1102, 1814(b), 1833(a), 1842(b), and (h), and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, as amended, 79 Stat. 296, 302, 310, 331; 86 Stat. 1395, 1454; 42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1).

[32 FR 12599, Aug. 31, 1967]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 405.502, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 405.503 Determining customary charges.

(a) *Customary charge defined.* The term ''customary charges'' will refer to the uniform amount which the individual physician or other person charges in the majority of cases for a specific medical procedure or service. In determining such uniform amount, token charges for charity patients and substandard charges for welfare and other low income patients are to be excluded. The reasonable charge cannot, except as provided in § 405.506, be higher than the individual physician's or other person's customary charge. The customary charge for different physicians or other persons may, of course, vary. Payment for covered services would be based on the actual charge for the service when, in a given instance, that charge is less than the amount which the carrier would otherwise have found to be within the limits of acceptable charges for the particular service. Moreover, the income of the individual beneficiary is not to be taken into account by the carrier in determining the amount which is considered to be a reasonable charge for a service rendered to him. There is no provision in the law for a carrier to evaluate the reasonableness of charges in light of an individual beneficiary's economic status.

(b) *Variation of charges.* If the individual physician or other person varies his charges for a specific medical procedure or service, so that no one amount is charged in the majority of cases, it will be necessary for the carrier to exercise judgment in the establishment of a ''customary charge'' for such physician or other person. In making this judgment, an important guide, to be utilized when a sufficient volume of data on the physician's or other person's charges is available, would be the median or midpoint of his charges, excluding token and substandard charges as well as exceptional charges on the high side. A significant clustering of charges in the vicinity of the median amount might indicate that a point of such clustering should be taken as the physician's or other person's ''customary'' charge. Use of

relative value scales will help in arriving at a decision in such instances.

(c) *Use of relative value scales.* If, for a particular medical procedure or service, the carrier is unable to determine the customary charge on the basis of reliable statistical data (for example, because the carrier does not yet have sufficient data or because the performance of the particular medical procedure or service by the physician or other person is infrequent), the carrier may use appropriate relative value scales to determine the customary charge for such procedure or service in relation to customary charges of the same physician or person for other medical procedures and services.

(d) *Revision of customary charge.* A physician's or other person's customary charge is not necessarily a static amount. Where a physician or other person alters his charges, a revised pattern of charges for his services may develop. Where on the basis of adequate evidence, the carrier finds that the physician or other person furnishing services has changed his charge for a service to the public in general, the customary charge resulting from the revised charge for the service should be recognized as the customary charge in making determinations of reasonable charges for such service when rendered thereafter to supplementary insurance beneficiaries. If the new customary charge is not above the top of the range of prevailing charges (see § 405.504(a)), it should be deemed to be reasonable by the carrier, subject to the provisions of § 405.508.

§ 405.504 Determining prevailing charges.

(a) *Ranges of charges.* (1) In the case of physicians' services furnished beginning January 1, 1987, the prevailing charges for a nonparticipating physician as defined in this paragraph will be no higher than the same level that was set for services furnished during the previous calendar year for a physician who was a participating physician during that year. A nonparticipating physician is a physician who has not entered into an agreement with the Medicare program to accept payment on an assignment-related basis (in accordance with § 424.55 of this chapter) for all items and services furnished to individuals enrolled under Part B of Medicare during a given calendar year.

(2) No charge for Part B medical or other health services may be considered to be reasonable if it exceeds the higher of:

(i) The prevailing charge for similar services in the same locality in effect on December 31, 1970, provided such prevailing charge had been found acceptable by CMS; or

(ii) The prevailing charge that, on the basis of statistical data and methodology acceptable to CMS, would cover:

(A) 75 percent of the customary charges made for similar services in the same locality during the 12-month period of July 1 through June 30 preceding the fee screen year (January 1 through December 31) in which the service was furnished; or

(B) In the case of services furnished more than 12 months before the beginning of the fee screen year (January 1 through December 31) in which the claim or request for payment is submitted, 75 percent of the customary charges made for similar services in the same locality during the 12 month period of July 1 through June 30 preceding the fee screen year that ends immediately preceding the fee screen year in which the claim or request for payment is submitted.

(3)(i) In the case of physicians' services, furnished before January 1, 1992, each prevailing charge in each locality may not exceed the prevailing charge determined for the FY ending June 30, 1973 (without reference to the adjustments made in accordance with the economic stabilization program then in effect), except on the basis of appropriate economic index data that demonstrate the higher prevailing charge level is justified by:

(A) Changes in general earnings levels of workers that are attributable to factors other than increases in their productivity; and

(B) changes in expenses of the kind incurred by physicians in office practice. The office-expense component and the earnings component of such index shall be given the relative weights shown in data on self-employed physicians' gross incomes.

Example. The available data indicate the office-expense and earnings components of the index should be given relative weights of 40 percent and 60 percent, respectively, and it is calculated that the aggregate increase in expenses of practice for a particular July through June period was 112 percent over the expenses of practice for calendar year 1971 and the increase in earnings (less increases in workers' productivity was 110 percent over the earnings for calendar year 1971. The allowable increase in any prevailing charge that could be recognized during the next fee screen year would be 110.8 percent ((.40×112)+(.60)×110)=110.8) above the prevailing charge recognized for fiscal year 1973.

(ii)(A) If the increase in the prevailing charge in a locality for a particular physician service resulting from an aggregate increase in customary charges for that service does not exceed the index determined under paragraph (a)(3)(i) of this section, the increase is permitted and any portion of the allowable increase not used is carried forward and is a basis for justifying increases in that prevailing charge in the future. However, if the increase in the prevailing charge exceeds the allowable increase, the increase will be reduced to the allowable amount. Further increases will be justified only to the degree that they do not exceed further rises in the economic index. The prevailing charge for physicians' services furnished during the 15-month period beginning July 1, 1984 may not exceed the prevailing charge for physicians' services in effect for the 12-month period beginning July 1, 1983. The increase in prevailing charges for physicians' services for subsequent fee screen years similarly may not reflect the rise in the economic index that would have otherwise been provided for the period beginning July 1, 1984, and must be treated as having fully provided for the rise in the economic index which would have been otherwise taken into account.

(B) Notwithstanding the provisions of paragraphs (a)(3)(i) and (ii)(A) of this section, the prevailing charge in the case of a physician service in a particular locality determined pursuant to paragraphs (a)(2) and (3)(i) of this section for the fiscal year beginning July 1, 1975, and for any subsequent fee screen years, if lower than the prevailing charge for the fiscal year ending June 30, 1975, by reason of the application of economic index data, must be raised to such prevailing charge which was in effect for the fiscal year ending June 30, 1975. (If the amount paid on any claim processed by a carrier after the original reasonable charge update for the fiscal year beginning July 1, 1975, and prior to the adjustments required by the preceding sentence, was at least $1 less than the amount due pursuant to the preceding sentence, the difference between the amount previously paid and the amount due shall be paid within 6 months after December 31, 1975; however, no payment shall be made on any claim where the difference between the amount previously and the amount due shall be paid within 6 months after December 31, 1975; however, no payment shall be made on any claim where the difference between the amount previously paid and the amount due is less than $1.)

(iii) If, for any reason, a prevailing charge for a service in a locality has no precise counterpart in the carrier's charge data for calendar year 1971 (the data on which the prevailing charge calculations for fiscal year 1973 were based), the limit on the prevailing charge will be estimated, on the basis of data and methodology acceptable to CMS, to seek to produce the effect intended by the economic index criterion. The allowance or reduction of an increase in a prevailing charge for any individual medical item or service may affect the allowance or reduction of an increase in the prevailing charges for other items or services if, for example, the limit on the prevailing charge is estimated, or if the prevailing charges for more than one item or service are established through the use of a relative value schedule and dollar conversion factors.

(b) *Variation in range of prevailing charges.* The range of prevailing charges in a locality may be different for physicians or other persons who engage in a specialty practice or service than for others. Existing differentials in the level of charges between different kinds of practice or service could, in some localities, lead to the development of more than one range of prevailing charges for application by

the carrier in its determinations of reasonable charges. Carrier decisions in this respect should be responsive to the existing patterns of charges by physicians and other persons who render covered services, and should establish differentials in the levels of charges between different kinds of practice or service only where in accord with such patterns.

(c) *Re-evaluation and adjustment of prevailing charges.* Determinations of prevailing charges by the carrier are to be re-evaluated and adjusted from time to time on the basis of factual information about the charges made by physicians and other persons to the public in general. This information should be obtained from all possible sources including a carrier's experience with its own programs as well as with the supplementary medical insurance program.

(d) *Computation and issuance of the MEI after CY 1992*—(1) For update years after CY 1992, the MEI is a physician input price index, in which the annual percent changes for the direct-labor price components are adjusted by an annual percent change in a 10-year moving average index of labor productivity in the nonfarm business sector.

(2) The MEI is constructed, using as a base year, CY 1989 weights and annual percent changes in the economic price proxies as shown on the following chart:

MEDICARE ECONOMIC INDEX EXPENDITURE CATEGORIES, WEIGHTS, AND PRICE PROXIES

Expense category	1989 weights [1,2] (percent)	Price proxy [3]
Total	100.0	
1. Physician's Own Time (net income, general earnings).	54.2	
a. Wages and Salaries	45.3	Average hourly earnings, total private non-farm.[4]
b. Fringe Benefits	8.8	Employment Cost Index, fringe benefits, private non-farm.[4]
2. Physician Practice Expense	45.8	
a. Non-physician Employee Compensation	16.3	
(1) Wages and Salaries	13.8	Employment Cost Index, wages and salaries weighted for occupational mix of non-physician employees.[4]
(2) Fringe Benefits	2.5	Employment Cost Index, fringe benefits, white collar.[4]
b. Office Expense	10.3	CPI-U, housing.
c. Medical Materials and Supplies	5.2	PPI, ethical drugs; PPI, surgical appliances and supplies; and CPI-U medical equipment and supplies (equally weighted).
d. Professional Liability Insurance	4.8	CMS survey of change in average liability premiums for $100,000/$300,000 liability coverage among 9 major insurers.
e. Medical Equipment	2.3	PPI, medical instruments and equipment.
f. Other Professional Expense	6.9	
(1) Professional Car	1.4	CPI-U, private transportation.
(2) Other	5.5	CPI-U, all items less food and energy.

[1] Sources: Martin L. Gonzalez, ed.: *Physician Marketplace Statistics, Fall, 1990.* Center for Health Policy Research, Chicago, American Medical Association, 1990; Mark Holoweiko, "Practice Expenses Take the Leap of the Decade," *Medical Economics,* November 12, 1990; and CMS, OACT special study.
[2] Due to rounding, weights may not sum to 100.0%
[3] All price proxies are for *annual* percent changes for the 12 months ending June 30th.
[4] Annual percent change values for Physicians' Own Time and Non-physician Employee Compensation are net of the change in the 10-year moving average of output per man-hour to exclude changes in non-farm business sector labor productivity.

(3) If there is no methodological change, CMS publishes a notice in the FEDERAL REGISTER to announce the annual increase in the MEI before the beginning of the update year to which it applies. If there are changes in the base year weights or price proxies, or if there are any other MEI methodological changes, they are published in the FEDERAL REGISTER with an opportunity for public comment.

[32 FR 12600, Aug. 31, 1967, as amended at 40 FR 25447, June 16, 1975; 42 FR 18275, Apr. 6, 1977. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 4430, Feb. 2, 1978; 47 FR 63274, Dec. 31, 1982; 51 FR 34978, Oct. 1, 1986; 53 FR 6648, Mar. 2, 1988; 57 FR 55912, Nov. 25, 1992]

§ 405.505 Determination of locality.

''Locality'' is the geographical area for which the carrier is to derive the reasonable charges or fee schedule amounts for services or items. Usually, a locality may be a State (including the District of Columbia, a territory, or a Commonwealth), a political or economic subdivision of a State, or a group of States. It should include a cross section of the population with respect to economic and other characteristics. Where people tend to gravitate toward certain population centers to obtain medical care or service, localities may be recognized on a basis constituting medical services areas (interstate or otherwise), comparable in concept to ''trade areas.'' Localities may differ in population density, economic level, and other major factors affecting charges for services. Carriers therefore shall delineate localities on the basis of their knowledge of local conditions. However, distinctions between localities are not to be so finely made that a locality includes only a very limited geographic area whose population has distinctly similar income characteristics (e.g., a very rich or very poor neighborhood within a city).

[57 FR 27305, June 18, 1992]

§ 405.506 Charges higher than customary or prevailing charges or lowest charge levels.

A charge which exceeds the customary charge of the physician or other person who rendered the medical or other health service, or the prevailing charge in the locality, or an applicable lowest charge level may be found to be reasonable, but only where there are unusual circumstances, or medical complications requiring additional time, effort or expense which support an additional charge, and only if it is acceptable medical or medical service practice in the locality to make an extra charge in such cases. The mere fact that the physician's or other person's customary charge is higher than prevailing would not justify a determination that it is reasonable.

(Secs. 1102, 1842(b) and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, 79 Stat. 302, 310, 331; 86 Stat. 1395, 1454; (42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1)))

[43 FR 32300, July 26, 1978]

§ 405.507 Illustrations of the application of the criteria for determining reasonable charges.

The following examples illustrate how the general criteria on customary charges and prevailing charges might be applied in determining reasonable charges under the supplementary medical insurance program. Basically, these examples demonstrate that, except where the actual charge is less, reasonable charges will reflect current customary charges of the particular physician or other person within the ranges of the current prevailing charges in the locality for that type and level of service:

The prevailing charge for a specific medical procedure ranges from $80 to $100 in a certain locality.

Doctor A's bill is for $75 although he customarily charges $80 for the procedure.

Doctor B's bill is his customary charge of $85

Doctor C's bill is his customary charge of $125

Doctor D's bill is for $100, although he customarily charges $80, and there are no special circumstances in the case.

The reasonable charge for Doctor A would be limited to $75 since under the law the reasonable charge cannot exceed the actual charge, even if it is lower than his customary charge and below the prevailing charges for the locality.

The reasonable charge for Doctor B would be $85, because it is his customary charge and it falls within the range of prevailing charges for that locality.

The reasonable charge for Doctor C could not be more than $100, the top of the range of prevailing charges.

The reasonable charge for Doctor D would be $80, because that is his customary charge. Even though his actual charge of $100 falls within the range of prevailing charges, the reasonable charge cannot exceed his customary charge in the absence of special circumstances.

§405.508 Determination of comparable circumstances; limitation.

(a) *Application of limitation.* The carrier may not in any case make a determination of reasonable charge which would be higher than the charge upon which it would base payment to its own policyholders for a comparable service in comparable circumstances. The charge upon which it would base payment, however, does not necessarily mean the amount the carrier would be obligated to pay. Under certain circumstances, some carriers pay amounts on behalf of individuals who are their policyholders, which are below the customary charges of physicians or other persons to other individuals. Payment under the supplementary medical insurance program would not be limited to these lower amounts.

(b) *When comparability exists.* ''Comparable circumstances,'' as used in the Act and this subpart, refers to the circumstances under which services are rendered to individuals and the nature of the carrier's health insurance programs and the method it uses to determine the amounts of payments under these programs. Generally, comparability would exist where:

(1) The carrier bases payment under its program on the customary charges, as presently constituted, of physicians or other persons and on current prevailing charges in a locality, and

(2) The determination does not preclude recognition of factors such as speciality status and unusual circumstances which affect the amount charged for a service.

(c) *Responsibility for determining comparability.* Responsibility for determining whether or not a carrier's program has comparability will in the first instance fall upon the carrier in reporting pertinent information about its programs to the Centers for Medicare & Medicaid Services. When the pertinent information has been reported, the Centers for Medicare & Medicaid Services will advise the carrier whether any of its programs have comparability.

§405.509 Determining the inflation-indexed charge.

(a) *Definition.* For purposes of this section, *inflation-indexed charge* means the lowest of the fee screens used to determine reasonable charges (as determined in §405.503 for the customary charge, §405.504 for the prevailing charge, this section for the inflation-indexed charge, and §405.511 for the lowest charge level) for services, supplies, and equipment reimbursed on a reasonable charge basis (excluding physicians' services), that is in effect on December 31 of the previous fee screen year, updated by the inflation adjustment factor, as described in paragraph (b) of this section.

(b) *Application of inflation adjustment factor to determine inflation-indexed charge.* (1) For fee screen years beginning on or after January 1, 1987, the inflation-indexed charge is determined by updating the fee screen used to determine the reasonable charges in effect on December 31 of the previous fee screen year by application of an inflation adjustment factor, that is, the annual change in the level of the consumer price index for all urban consumers, as compiled by the Bureau of Labor Statistics, for the 12-month period ending on June 30 of each year.

(2) For services, supplies, and equipment furnished from October 1, 1985 through December 31, 1986 the inflation adjustment factor is zero.

(c) The inflation-indexed charge does not apply to any services, supplies, or equipment furnished after December 31, 1991, that are covered under or limited by the fee schedule for physicians' services established under section 1848 of the Act and part 415 of this chapter. These services are subject to the Medicare Economic Index described in §415.30 of this chapter.

[51 FR 34979, Oct. 1, 1986; 51 FR 37911, Oct. 27, 1986, as amended at 56 FR 59621, Nov. 25, 1991]

§405.511 Reasonable charges for medical services, supplies, and equipment.

(a) *General rule.* (1) A charge for any medical service, supply, or equipment (including equipment servicing) that in the judgment of CMS generally does not vary significantly in quality from one supplier to another (and that is

identified by a notice published in the FEDERAL REGISTER) may not be considered reasonable if it exceeds:

(i) The customary charge of the supplier (see § 405.503);

(ii) The prevailing charge in the locality (see § 405.504);

(iii) The charge applicable for a comparable service and under comparable circumstances to the policyholders or subscribers of the carrier (see § 405.508);

(iv) The lowest charge level at which the item or service is widely and consistently available in the locality (see paragraph (c) of this section); or

(v) The inflation-indexed charge, as determined under § 405.509, in the case of medical services, supplies, and equipment that are reimbursed on a reasonable charge basis (excluding physicians' services).

(2) In the case of laboratory services, paragraph (a)(1) of this section is applicable to services furnished by physicians in their offices, by independent laboratories (see § 405.1310(a)) and to services furnished by a hospital laboratory for individuals who are neither inpatients nor outpatients of a hospital. Allowance of additional charges exceeding the lowest charge level can be approved by the carrier on the basis of unusual circumstances or medical complications in accordance with § 405.506.

(b) *Public notice of items and services subject to the lowest charge level rule.* Before the Secretary determines that lowest charge levels should be established for an item or service, notice of the proposed determination will be published with an opportunity for public comment. The descriptions or specifications of items or services in the notice will be in sufficient detail to permit a determination that items or services conforming to the descriptions will not vary significantly in quality.

(c) *Calculating the lowest charge level.* The lowest charge level at which an item or service is widely and consistently available in a locality is calculated by the carrier in accordance with instructions from CMS as follows:

(1) *For items or services furnished on or before December 31, 1986.* (i) A lowest charge level is calculated for each identified item or service in January and July of each year.

(ii) The lowest charge level for each identified item or service is set at the 25th percentile of the charges (incurred or submitted on claims processed by the carrier) for that item or service, in the locality designated by the carrier for this purpose, during the second calendar quarter preceding the determination date. Accordingly, the January calculations will be based on charges for the July through September quarter of the previous calendar year, and the July calculations will be based on charges for the January through March quarter of the same calendar year.

(2) *For items or services furnished on or after January 1, 1987.* (i) A lowest charge level is calculated for each identified item or service in January of each year.

(ii) The lowest charge level for each identified item or service is set at the 25th percentile of the charges (incurred or submitted on claims processed by the carrier) for that item or service, in the locality designated by the carrier for this purpose, during the 3-month period of July 1 through September 30 preceding the fee screen year (January 1 through December 31) for which the item or service was furnished.

(3) *Lowest charge levels for laboratory services.* In setting lowest charge levels for laboratory services, the carrier will consider only charges made for laboratory services performed by physicians in their offices, by independent laboratories which meet coverage requirements, and for services furnished by a hospital laboratory for individuals who are neither inpatients nor outpatients of a hospital.

(d) *Locality.* Subject to the approval of the Secretary, the carrier may designate its entire service area as the locality for purposes of this section, or may otherwise modify the localities used for calculating prevailing charges. (The modified locality for an item or service will also be used for calculating the prevailing charge for that item or service.)

(Secs. 1102, 1842(b) and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, 79 Stat. 302, 310, 331, 86 Stat. 1395, 1454 (42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1)))

[43 FR 32300, July 26, 1978, as amended at 50 FR 40174, Oct. 1, 1985; 51 FR 34979, Oct. 1, 1986]

§405.512 Carriers' procedural terminology and coding systems.

(a) *General.* Procedural terminology and coding systems are designed to provide physicians and third party payers with a common language that accurately describes the kinds and levels of services provided and that can serve as a basis for coverage and payment determinations.

(b) *Modification of terminology and/or coding systems.* A carrier that wishes to modify its system of procedural terminology and coding shall submit its request to the Centers for Medicare & Medicaid Services with all pertinent data and information for approval before the revision is implemented. The Centers for Medicare & Medicaid Services will evaluate the proposal in the light of the guidelines specified in paragraph (c) of this section and such other considerations as may be pertinent, and consult with the Assistant Secretary for Health. The Centers for Medicare & Medicaid Services will approve such a revision if it determines that the potential advantages of the proposed new system, outweigh the disadvantages.

(c) *Guidelines.* The following considerations and guidelines are taken into account in evaluating a carrier's proposal to change its system of procedural terminology and coding:

(1) The rationale for converting to the new terminology and coding;

(2) The estimated short-run and long-run impact on the cost of the health insurance program, other medical care costs, administrative expenses, and the reliability of the estimates;

(3) The degree to which the conversion to the proposed new terminology and coding can be accomplished in a way that permits full implementation of the reasonable charge criteria in accordance with the provisions of this subpart;

(4) The degree to which the proposed new terminology and coding are accepted by physicians in the carrier's area (physician acceptance is assumed only if a majority of the Medicare and non-Medicare bills and claims completed by physicians in the area and submitted to the carrier can reasonably be expected to utilize the proposed new terminology and coding);

(5) The extent to which the proposed new terminology and coding system is used by the carrier in its non-Medicare business;

(6) The clarity with which the proposed system defines its terminology and whether the system lends itself to:

(i) Accurate determinations of coverage;

(ii) Proper assessment of the appropriate level of payment; and

(iii) Meeting the carrier's or Professional Standards Review Organizations' review needs and such other review needs as may be appropriate;

(7) Compatibility of the new terminology and coding system with other systems that the carrier and other carriers may utilize in the administration of the Medicare program—e.g., its compatibility with systems and statistical requirements and with the historical data in the carrier's processing system; and

(8) Compatibility of the proposed system with the carriers methods for determining payment under the fee schedule for physicians' services for services which are identified by a single element of terminology but which may vary in content.

[40 FR 7639, Feb. 21, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 10298, Mar. 4, 1994]

§405.515 Reimbursement for clinical laboratory services billed by physicians.

This section implements section 1842(h) of the Social Security Act, which places a limitation on reimbursement for markups on clinical laboratory services billed by physicians. If a physician's bill, or a request for payment for a physician's services, includes a charge for a laboratory test for which payment may be made under this part, the amount payable with respect to the test shall be determined as follows (subject to the coinsurance and deductible provisions at §§410.152 and 410.160 of this chapter):

(a) If the bill or request for payment indicates that the test was personally performed or supervised either by the physician who submitted the bill (or for whose services the request for payment was made), or by another physician with whom that physician shares

his or her practice, the payment will be based on the physician's reasonable charge for the test (as determined in accordance with § 405.502).

(b) If the bill or request for payment indicates that the test was performed by an outside laboratory, and identifies both the laboratory and the amount the laboratory charged, payment for the test will be based on the lower of—

(1) The laboratory's reasonable charge for the service (as determined in accordance with § 405.502), or

(2) The amount that the laboratory charged the physician for the service.

(c) If the bill or request for payment does not indicate that the conditions specified in paragraph (a) of this section were met, and does not identify both the laboratory and the amount the laboratory charged, payment will be based on the lowest charge at which the carrier estimates the test could have been secured from a laboratory serving the physician's locality. The carrier will estimate this lowest amount twice a year by (i) obtaining lists of charges laboratories make to physicians from as many commercial laboratories serving the carrier's area as possible (including laboratories in other States from which tests may be obtained by physicians in the carrier's service area) and (ii) establishing a schedule of lowest prices based on this information. The carrier will take into consideration specific circumstances, such as a need for emergency services that may be costlier than routine services, in making the estimate in a particular case. However, in no case may this estimate be higher than the lowest customary charge for commercial laboratories, or when applicable to the laboratory service, the lowest charge level determined in accordance with § 405.511, in the carrier's service area.

(d) When a physician bills, in accordance with paragraph (b) or (c) of this section, for a laboratory test and indicates that it was performed by an independent laboratory, a nominal payment will also be made to the physician for collecting, handling, and shipping the specimen to the laboratory, if the physician bills for such a service.

[46 FR 42672, Aug. 24, 1981, as amended at 51 FR 41351, Nov. 14, 1986]

§ 405.517 Payment for drugs and biologicals that are not paid on a cost or prospective payment basis.

(a) *Applicability*—(1) *Payment for drugs and biologicals before January 1, 2004.* Payment for a drug or biological that is not paid on a cost or prospective payment basis is determined by the standard methodology described in paragraph (b) of this section. Examples of when this procedure applies include a drug or biological furnished incident to a physician's service, a drug or biological furnished by an independent dialysis facility that is not included in the ESRD composite rate set forth in § 413.170(c) of this chapter, and a drug or biological furnished as part of the durable medical equipment benefit.

(2) *Payment for drugs and biologicals on or after January 1, 2004.* Effective January 1, 2004, payment for drugs and biologicals that are not paid on a cost or prospective payment basis are paid in accordance with Part 414, subpart I of this chapter.

(3) *Payment for drugs and biologicals on or after January 1, 2005.* Effective January 1, 2005, payment for drugs and biologicals that are not paid on a cost or prospective payment basis are paid in accordance with part 414, subpart K of this chapter.

(b) *Methodology.* Payment for a drug or biological described in paragraph (a) of this section is based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological.

(c) *Multiple-source drugs.* For multiple-source drugs and biologicals, for purposes of this regulation, the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological.

[63 FR 58905, Nov. 2, 1998, as amended at 69 FR 1116, Jan. 7, 2004; 69 FR 66420, Nov. 15, 2004]

§405.520 Payment for a physician assistant's, nurse practitioner's, and clinical nurse specialists' services and services furnished incident to their professional services.

(a) *General rule.* A physician assistant's, nurse practitioner's, and clinical nurse specialists' services, and services and supplies furnished incident to their professional services, are paid in accordance with the physician fee schedule. The payment for a physician assistants' services may not exceed the limits at §414.52 of this chapter. The payment for a nurse practitioners' and clinical nurse specialists' services may not exceed the limits at §414.56 of this chapter.

(b) *Requirements.* Medicare payment is made only if all claims for payment are made on an assignment-related basis in accordance with §424.55 of this chapter, that sets forth, respectively, the conditions for coverage of physician assistants' services, nurse practitioners' services and clinical nurse specialists' services, and services and supplies furnished incident to their professional services.

(c) *Civil money penalties.* Any person or entity who knowingly and willingly bills a Medicare beneficiary amounts in excess of the appropriate coinsurance and deductible is subject to a civil money penalty as described in §§402.1(c)(11), 402.105(d)(2)(viii), and 402.107(b)(8) of this chapter.

[63 FR 58905, Nov. 2, 1998, as amended at 66 FR 49547, Sept. 28, 2001]

§405.534 Limitation on payment for screening mammography services.

The provisions in paragraphs (a), (b), and (c) of this section apply for services provided from January 1, 1991 until December 31, 2001. Screening mammography services provided after December 31, 2001 are paid under the physician fee schedule in accordance with §414.2 of this chapter.

(a) *Basis and scope.* This section implements section 1834(c) of the Act by establishing a limit on payment for screening mammography examinations. There are three categories of billing for screening mammography services. Those categories and the payment limitations on each are set forth in paragraphs (b) through (d) of this section.

(b) *Global or complete service billing representing both the professional and technical components of the procedure.* If a fee is billed for a global service, the amount of payment subject to the deductible is equal to 80 percent of the least of the following:

(1) The actual charge for the service.

(2) The amount established for the global procedure for a diagnostic bilateral mammogram under the fee schedule for physicians' services set forth at part 414, subpart A.

(3) The payment limit for the procedure. For screening mammography services furnished in CY 1994, the payment limit is $59.63. On January 1 of each subsequent year, the payment limit is updated by the percentage increase in the Medicare Economic Index (MEI) and reflects the relationship between the relative value units for the professional and technical components of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(c) *Professional component billing representing only the physician's interpretation for the procedure.* If the professional component of screening mammography services is billed separately, the amount of payment for that professional component, subject to the deductible, is equal to 80 percent of the least of the following:

(1) The actual charge for the professional component of the service.

(2) The amount established for the professional component of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(3) The professional component of the payment limit for screening mammography services described in paragraph (b)(3) of this section.

(d) *Technical component billing representing other resources involved in furnishing the procedure.* If the technical component of screening mammography services is billed separately, the amount of payment, subject to the deductible, is equal to 80 percent of the least of the following:

(1) The actual charge for the technical component of the service.

(2) The amount established for the technical component of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(3) The technical component of the payment limit for screening mammography services described in paragraph (b)(3) of this section.

[55 FR 53521, Dec. 31, 1990, as amended at 59 FR 49833, Sept. 30, 1994; 66 FR 55328, Nov. 1, 2001]

§ 405.535 Special rule for nonparticipating physicians and suppliers furnishing screening mammography services before January 1, 2002.

The provisions in this section apply for screening mammography services provided from January 1, 1991 until December 31, 2001. Screening mammography services provided after December 31, 2001 are physician services pursuant to §414.2 of this chapter paid under the physician fee schedule. If screening mammography services are furnished to a beneficiary by a nonparticipating physician or supplier that does not accept assignment, a limiting charge applies to the charges billed to the beneficiary. The limiting charge is the lesser of the following:

(a) 115 percent of the payment limit set forth in §405.534(b)(3), (c)(3), and (d)(3) (limitations on the global service, professional component, and technical component of screening mammography services, respectively).

(b) The limiting charge for the global service, professional component, and technical component of a diagnostic bilateral mammogram under the fee schedule for physicians' services set forth at §414.48(b) of this chapter.

[59 FR 49833, Sept. 30, 1994, as amended at 62 FR 59098, Oct. 31, 1997; 66 FR 55328, Nov. 1, 2001]

Subpart F [Reserved]

Subpart G—Reconsiderations and Appeals Under Medicare Part A

AUTHORITY: Secs. 1102, 1155, 1869(b), 1871, 1872, and 1879 of the Social Security Act (42 U.S.C. 1302, 1320c–4, 1395ff(b), 1395hh, 1395ii, and 1395pp).

SOURCE: 37 FR 5814, Mar. 22, 1972, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.701 Basis, purpose and definitions.

(a) This subpart implements section 1869 of the Social Security Act. Section 1869(a) provides that the Secretary will make determinations about the following matters, and section 1869(b) provides for a hearing for an individual who is dissatisfied with the Secretary's determination as to:

(1) Whether the individual is entitled to hospital insurance (part A) or supplementary medical insurance (part B) under title XVIII of the Act; or

(2) The amount payable under hospital insurance.

(b) This subpart establishes the procedures governing initial determinations, reconsidered determinations, hearings, and final agency review, and the reopening of determinations and decisions that are applicable to matters arising under paragraph (a) of this section.

(c) Subparts J and R of 20 CFR part 404 (dealing with determinations, the administrative review process and representation of parties) are also applicable to matters arising under paragraph (a) of this section, except to the extent that specific provisions are contained in this subpart.

(d) *Definitions.* As used in subpart G of this part, the term—

Appellant designates the beneficiary, provider or other person or entity that has filed an appeal concerning a particular determination of benefits under Medicare part A. Designation as an appellant does not in itself convey standing to appeal the determination in question.

Common issues of law and fact, with respect to the aggregation of claims by two or more appellants to meet the minimum amount in controversy needed for a hearing, occurs when the claims sought to be aggregated are denied or reduced for similar reasons and arise from a similar fact pattern material to the reason the claims are denied.

Delivery of similar or related services, with respect to the aggregation of claims by two or more provider appellants to meet the minimum amount in

controversy needed for a hearing, means like or coordinated services or items provided to the same beneficiary by the appellants.

[55 FR 11020, Mar. 26, 1990, as amended at 59 FR 12181, Mar. 16, 1994]

§405.702 Notice of initial determination.

After a request for payment under part A of title XVIII of the Act is filed with the intermediary by or on behalf of the individual who received inpatient hospital services, extended care services, or home health services, and the intermediary has ascertained whether the items and services furnished are covered under part A of title XVIII, and where appropriate, ascertained and made payment of amounts due or has ascertained that no payments were due, the individual will be notified in writing of the initial determination in his case. In addition, if the items or services furnished such individual are not covered under part A of title XVIII by reason of §411.15(g) or §411.15(k) and payment may not be made for such items or services under §411.400 only because the requirements of §411.400(a)(2) are not met, the provider of services which furnished such items or services will be notified in writing of the initial determination in such individual's case. These notices shall be mailed to the individual and the provider of services at their last known addresses and shall state in detail the basis for the determination. Such written notices shall also inform the individual and the provider of services of their right to reconsideration of the determination if they are dissatisfied with the determination.

[55 FR 11020, Mar. 26, 1990]

§405.704 Actions which are initial determinations.

(a) *Applications and entitlement of individuals.* An initial determination with respect to an individual includes the following—

(1) A determination with respect to entitlement to hospital insurance or supplementary medical insurance;

(2) A disallowance of an individual's application for entitlement to hospital or supplementary medical insurance, if the individual fails to submit evidence requested by SSA to support the application. (SSA will specify in the initial determination the conditions of entitlement that the applicant failed to establish by not submitting the requested evidence);

(3) A denial of a request for withdrawal of an application for hospital or supplementary medical insurance;

(4) A denial of a request for cancellation of a ''request for withdrawal''; and

(5) A determination as to whether an individual, previously determined to be entitled to hospital or supplementary medical insurance, is no longer entitled to such benefits, including a determination based on nonpayment of premiums.

(b) *Requests for payment by or on behalf of individuals.* An initial determination with respect to an individual includes any determination made on the basis of a request for payment by or on behalf of the individual under part A of Medicare, including a determination with respect to:

(1) The coverage of items and services furnished;

(2) The amount of an applicable deductible;

(3) The application of the coinsurance feature;

(4) The number of days of inpatient hospital benefits utilized during a spell of illness or for purposes of the inpatient psychiatric hospital 190-day lifetime maximum;

(5) The number of days of the 60-day lifetime reserve utilized for inpatient hospital coverage;

(6) The number of days of posthospital extended care benefits utilized;

(7) The number of home health visits utilized;

(8) The physician certification requirement;

(9) The request for payment requirement;

(10) The beginning and ending of a spell of illness, including a determination made under the presumptions established under §409.60(c)(2) of this chapter, as specified in §409.60(c)(4) of this chapter.

(11) The medical necessity of services (See parts 466 and 473 of this chapter for provisions pertaining to initial and

reconsidered determinations made by a QIO);

(12) When services are excluded from coverage as custodial care (§ 411.15(g)) or as not reasonable and necessary (§ 411.15(k)), whether the individual or the provider of services who furnished the services, or both, knew or could reasonably have been expected to know that the services were excluded from coverage (see § 411.402);

(13) Any other issues having a present or potential effect on the amount of benefits to be paid under part A of Medicare, including a determination as to whether there has been an overpayment or underpayment of benefits paid under part A, and if so, the amount thereof; and

(14) Whether a waiver of adjustment or recovery under sections 1870 (b) and (c) of the Act is appropriate when an overpayment of hospital insurance benefits or supplementary medical insurance benefits (including a payment under section 1814(e) of the Act) has been made with respect to an individual.

(c) *Initial determination with respect to a provider of services.* An initial determination with respect to a provider of services shall be a determination made on the basis of a request for payment filed by the provider under part A of Medicare on behalf of an individual who was furnished items or services by the provider, but only if the determination involves the following:

(1) A finding by the intermediary that such items or services are not covered by reason of § 411.15(g) or § 411.15(k); and

(2) A finding by the intermediary that either such individual or such provider of services, or both, knew or could reasonably have been expected to know that such items or services were excluded from coverage under the program.

[55 FR 11020, Mar. 26, 1990]

§ 405.705 Actions which are not initial determinations.

An initial determination under Part A of Medicare does not include determinations relating to:

(a) The reasonable cost of items or services furnished under Part A of Medicare;

(b) Whether an institution or agency meets the conditions for participation in the program;

(c) Whether an individual is qualified for use of the expedited appeals process as provided in § 405.718;

(d) An action regarding compromise of a claim arising under the Medicare program, or termination or suspension of collection action on such a claim under the Federal Claims Collection Act of 1966 (31 U.S.C. 3711). See 20 CFR 404.515 for overpayment claims against an individual, § 405.376 for overpayment claims against a provider, physician or other supplier, and § 408.110 for claims concerning unpaid Medicare premiums;

(e) The transfer or discharge of residents of skilled nursing facilities in accordance with § 483.12 of this chapter; or

(f) The preadmission screening and annual resident review processes required by part 483 subparts C and E of this chapter.

[45 FR 73932, Nov. 7, 1980; 46 FR 24565, May 1, 1981, as amended at 52 FR 22454, June 12, 1987; 52 FR 48123, Dec. 18, 1987; 57 FR 56504, Nov. 30, 1992; 61 FR 63749, Dec. 2, 1996]

§ 405.706 Decisions of utilization review committees.

(a) *General rule.* A decision of a utilization review committee is a medical determination by a staff committee of the provider or a group similarly composed and does not constitute a determination by the Secretary within the meaning of section 1869 of the Act. The decision of a utilization review committee may be considered by CMS along with other pertinent medical evidence in determining whether or not an individual has the right to have payment made under Part A of title XVIII.

(b) *Applicability under the prospective payment system.* CMS may consider utilization review committee decisions related to inpatient hospital services paid for under the prospective payment system (see part 412 of this chapter) only as those decisions concern:

(1) The appropriateness of admissions resulting in payments under subparts D, E and G of part 412 of this chapter.

(2) The covered days of care involved in determinations of outlier payments under § 412.80(a)(1)(i) of this chapter; and

(3) The necessity of professional services furnished in high cost outliers under §412.80(a)(1)(ii) of this chapter.

[48 FR 39831, Sept. 1, 1983]

§405.708 Effect of initial determination.

(a) The initial determination under §405.704 (a) or (b) shall be binding upon the individual on whose behalf payment under part A has been requested or, if such individual is deceased, upon the representative of such individual's estate, unless it is reconsidered in accordance with §§405.710 through 405.717 or revised in accordance with §405.750. Such individual (or the representative of such individual's estate if the individual is deceased) shall be the party to such initial determination.

(b) The initial determination under §405.704(c) shall be binding upon the provider of services unless it is reconsidered in accordance with §§405.710 through 405.717 or revised in accordance with §405.750. Such provider of services shall be the party to such initial determination.

[55 FR 11021, Mar. 26, 1990, as amended at 62 FR 25855, May 12, 1997]

§405.710 Right to reconsideration.

(a) An individual who is a party to an initial determination, as specified in §405.704 (a) and (b), (or if such individual is deceased, the representative of such individual's estate) and who is dissatisfied with the initial determination may request a reconsideration of such determination in accordance with §405.711 regardless of the amount in controversy.

(b) A provider of services who is a party to an initial determination (as specified in §405.704(c)) and who is dissatisfied with such initial determination may request a reconsideration of such determination in accordance with §405.711, regardless of the amount in controversy, but only if the individual on whose behalf the request for payment was made has indicated in writing that he does not intend to request reconsideration of the intermediary's initial determination on such request for payment, or if the intermediary has made a finding (see §405.704(c)) that such individual did not know or could not reasonably have been expected to know that the expenses incurred for the items or services for which such request for payment was made were not reimbursable by reason of §411.15(g) or §411.15(k).

[55 FR 11021, Mar. 26, 1990]

§405.711 Time and place of filing request for reconsideration.

The request for reconsideration shall be made in writing and filed at an office of the SSA or the CMS or, in the case of a qualified railroad retirement beneficiary (see 20 CFR 404.368) filed at an office of the Railroad Retirement Board, within 60 days after the date of receipt of notice of initial determination, unless such time is extended as provided in §405.712. A request for reconsideration which is filed with the intermediary which received the request for payment submitted on behalf of the individual is considered to have been filed with the CMS as of the date it is filed with the intermediary. For purposes of this section, the date of receipt of notice of the initial determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary.

[41 FR 47917, Nov. 1, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§405.712 Extension of time to request reconsideration.

If a party to an initial determination desires to file a request for reconsideration after the time for filing such request in accordance with §405.711 has passed, such party may file a petition with the SSA or the CMS or, in the case of a qualified railroad retirement beneficiary, with the Railroad Retirement Board, for an extension of time for the filing of such request. Such petition shall be in writing and shall state the reasons why the request for reconsideration was not filed within the required time. For good cause shown, the CMS may extend the time for filing the request for reconsideration.

[37 FR 5814, Mar. 22, 1972. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§ 405.714 Withdrawal of request for reconsideration.

A request for reconsideration may be withdrawn by the party to the initial determination who filed the request or by his representative provided that the withdrawal is made in writing and filed at an office of the SSA or the CMS or, in the case of a qualified railroad retirement beneficiary, with the Railroad Retirement Board prior to the date of the mailing of the notice of reconsidered determination. A withdrawal filed with the intermediary which received the request for payment submitted on behalf of the individual is considered to have been filed with the CMS as of the date it is filed with the intermediary.

[40 FR 1025, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§ 405.715 Reconsidered determination.

(a) In reconsidering an initial determination, the CMS shall review such initial determination, the evidence and findings upon which such determination was based, and any additional evidence submitted to the SSA or the CMS or otherwise obtained by the intermediary or the CMS; and shall make a determination affirming or revising, in whole or in part, such initial determination.

(b) If the request for reconsideration is filed by an individual with respect to an initial determination specified in § 405.704(b)(12), the provider of services who furnished the items or services shall, prior to the making of the reconsidered determination, be made a party thereto. If pursuant to § 405.710(b) a request for reconsideration is filed by a provider of services with respect to an individual determination under § 405.704(c), the individual who was furnished the items or services shall, prior to the making of the reconsidered determination, be made a party thereto.

[55 FR 11021, Mar. 26, 1990, as amended at 62 FR 25855, May 12, 1997]

§ 405.716 Notice of reconsidered determination.

Written notice of the reconsidered determination shall be mailed by the CMS to the parties and their representatives at their last known addresses. Such notice shall state the specific reasons for the reconsidered determination and shall advise the parties of their right to a hearing if the amount in controversy is $100 or more, or, if appropriate, advise them of the requirements for use of the expedited appeals process (see § 405.718).

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§ 405.717 Effect of a reconsidered determination.

The reconsidered determination is binding upon all parties unless—

(a) A request for a hearing is filed with SSA or CMS within 60 days after the date of receipt of notice of the reconsidered determination by the parties (for purposes of this section, the date of receipt of notice of the reconsidered determination is presumed to be 5 days after the date of the notice, unless it is shown that the notice was received earlier or later); or

(b) The reconsidered determination is revised in accordance with § 405.750; or

(c) The expedited appeals process is used in accordance with § 405.718.

[62 FR 25852, May 12, 1997]

§ 405.718 Expedited appeals process.

(a) *Conditions for use of expedited appeals process (EAP).* A party may use the EAP to request court review in place of an administrative law judge (ALJ) hearing or Departmental Appeals Board (DAB) review if the following conditions are met:

(1) CMS has made a reconsideration determination; an ALJ has made a hearing decision; or DAB review has been requested, but a final decision has not been issued.

(2) The filing entity is a party referred to in § 405.718(d).

(3) The party has filed a request for an ALJ hearing in accordance with § 405.722, or DAB review in accordance with 20 CFR 404.968.

(4) The amount remaining in controversy is $1,000 or more.

(5) If there is more than one party to the reconsideration determination or hearing decision, each party concurs, in writing, with the request for the EAP.

(b) *Content of the request for EAP.* The request for the EAP:

(1) Alleges that there are no material issues of fact in dispute; and

(2) Asserts that the only factor precluding a decision favorable to the party is a statutory provision that is unconstitutional or a regulation, national coverage decision under section 1862(a)(1) of the Act, or CMS Ruling that is invalid.

(c) *Place and time for requesting an EAP*—(1) *Place for filing request.* The person must file a written request—

(i) At an office of SSA or CMS; or

(ii) If the person is in the Philippines, at the Veterans Administration Regional Office or with an ALJ; or

(iii) If the person is a qualified railroad retirement beneficiary, at an office of the Railroad Retirement Board.

(2) *Time of filing request.* The party may file a request for the EAP—

(i) If the party has requested a hearing, at any time prior to receipt of the notice of the ALJ's decision;

(ii) Within 60 days after the date of receipt of notice of the ALJ's decision or dismissal, unless the time is extended in accordance with the standards set out in 20 CFR 404.925(c). For purposes of this section, the date of receipt of the notice is presumed to be 5 days after the date on the notice, unless it is shown that the notice was received later; or

(iii) If the party has requested DAB review, at any time prior to receipt of notice of the Board's decision.

(d) *Parties to the EAP.* The parties to the EAP are the persons who were parties to the reconsideration determination and, if appropriate, to the hearing.

(e) *Determination on request for EAP.* (1) For EAP requests initiated at the ALJ level, an ALJ determines whether all conditions of paragraphs (a) and (b) of this section are met.

(2) If a hearing decision has been issued, the DAB determines whether all conditions of paragraphs (a) and (b) of this section are met.

(f) *ALJ or DAB certification for the EAP.* If the party meets the requirements for the EAP, the ALJ or the DAB, as appropriate, certifies the case in writing stating that:

(1) The facts involved in the claim are not in dispute;

(2) Except as indicated in paragraph (f)(3) of this section, CMS's interpretation of the law is not in dispute;

(3) The sole issue(s) in dispute is the constitutionality of a statutory provision or the validity of a regulation, CMS Ruling, or national coverage decision based on section 1862(a)(1) of the Act.

(4) Except for the provision challenged, the right(s) of the party is established; and

(5) The determination or decision made by the ALJ or DAB is final for purposes of seeking judicial review.

(g) *Effect of ALJ or DAB certification.* (1) Following the issuance of the certification described in paragraph (f) of this section, the party waives completion of the remaining steps of the administrative appeals process.

(2) The 60-day period for filing a civil suit in a Federal district court begins on the date of receipt of the ALJ or DAB certification.

(h) *Effect of a request for EAP that does not result in certification.* If a request for the EAP does not meet all the conditions for use of the process, the ALJ or DAB so advises the party and treats the request as a request for hearing or DAB review, as appropriate.

[62 FR 25852, May 12, 1997]

§405.720 Hearing; right to hearing.

A person has a right to a hearing regarding any initial determination made under §405.704 if:

(a) Such initial determination has been reconsidered by the CMS;

(b) Such person was a party to the reconsidered determination;

(c) Such person or his representative has filed a written request for a hearing in accordance with the procedure described in §405.722; and

(d) The amount in controversy is $100 or more.

[40 FR 1025, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§405.722 Time and place of filing request for a hearing.

The request for a hearing shall be made in writing and filed at an office of the SSA or the CMS or with a ALJ, or, in the case of a qualified railroad retirement beneficiary, at an office of

the Railroad Retirement Board. Such request must be filed within 60 days after the date of receipt of notice of the reconsidered determination by such individual, except where the time is extended as provided in 20 CFR 404.933(c). For purposes of this section, the date of receipt of notice of the reconsidered determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary.

[45 FR 73933, Nov. 7, 1980, as amended at 62 FR 25855, May 12, 1997]

§ 405.724 Departmental Appeals Board (DAB) review.

Regulations beginning at 20 CFR 404.967 regarding SSA Appeals Council Review are also applicable to DAB review of matters addressed by this subpart.

[62 FR 25852, May 12, 1997]

§ 405.730 Court review.

(a) To the extent authorized by sections 1869, 1876(c)(5)(B), and 1879(d) of the Act, a party to a Departmental Appeals Board (DAB) decision or an ALJ decision if the DAB does not review the ALJ decision, may obtain a court review if the amount remaining in controversy is $1,000 or more. A party may obtain court review by filing a civil action in a district court of the United States in accordance with the provisions of section 205(g) of the Act. The filing procedure is set forth at 20 CFR 422.210.

(b) A party to a reconsidered determination or an ALJ hearing decision may obtain a court review if the amount in controversy is $1,000 or more, and he or she requests and meets the conditions for the expedited appeals process set forth in § 405.718.

[62 FR 25852, May 12, 1997]

§ 405.732 Review of a national coverage determination (NCD).

(a) *General rule.* (1) An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under title XVIII of the Act.

(2) An NCD does not include a determination of what code, if any, is assigned to a particular item or service covered under title XVIII or a determination for the amount of payment made for a particular item or service.

(3) NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act.

(4) An NCD is binding on all Medicare carriers, fiscal intermediaries, QIOs, HMOs, CMPs, HCPPs, the Medicare Appeals Council, and ALJs.

(b) *Review by ALJ.* (1) An ALJ may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD has been applied correctly to the claim.

(c) *Review by Court.* For initial determinations and NCD challenges under section 1862(a)(1) of the Act, arising before October 1, 2002, a court's review of an NCD is limited to whether the record is incomplete or otherwise lacks adequate information to support the validity of the decision, unless the case has been remanded to the Secretary to supplement the record regarding the NCD. In these cases, the court may not invalidate an NCD except upon review of the supplemental record.

[68 FR 63715, Nov. 7, 2003]

§ 405.740 Principles for determining the amount in controversy.

(a) *Individual appellants.* For the purpose of determining whether an individual appellant meets the minimum amount in controversy needed for a hearing ($100), the following rules apply:

(1) The amount in controversy is computed as the actual amount charged the individual for the items and services in question, less any amount for which payment has been made by the intermediary and less any deductible and coinsurance amounts applicable in the particular case.

(2) A single beneficiary may aggregate claims from two or more providers to meet the $100 hearing threshold and a single provider may aggregate claims for services provided to one or more beneficiaries to meet the $100 hearing threshold.

(3) In either of the circumstances specified in paragraph (a)(2) of this section, two or more claims may be aggregated by an individual appellant only if the claims have previously been reconsidered and a request for hearing has been made within 60 days after receipt of the reconsideration determination(s).

(4) When requesting a hearing, the appellant must specify in his or her appeal request the specific claims to be aggregated.

(b) *Two or more appellants.* As specified below, under section 1869(b)(2) of the Act, two or more appellants may aggregate their claims together to meet the minimum amount in controversy needed for a hearing ($100). The right to aggregate under this statutory provision applies to claims for items and services furnished on or after January 1, 1987.

(1) The aggregate amount in controversy is computed as the actual amount charged the individual(s) for the items and services in question, less any amount for which payment has been made by the intermediary and less any deductible and coinsurance amounts applicable in the particular case.

(2) In determining the amount in controversy, two or more appellants may aggregate their claims together under the following circumstances:

(i) Two or more beneficiaries may combine claims representing services from the same or different provider(s) if the claims involve common issues of law and fact;

(ii) Two or more providers may combine their claims if the claims involve the delivery of similar or related services to the same beneficiary; or

(iii) Two or more providers may combine their claims if the claims involve common issues of law and fact with respect to services furnished to two or more beneficiaries.

(iv) In any of the circumstances specified in paragraphs (b)(2)(i) through (b)(2)(iii) of this section, the claims may be aggregated only if the claims have previously been reconsidered and a request for hearing has been made within 60 days after receipt of the reconsideration determination(s). Moreover, in the request for hearing, the appellants must specify the claims that they seek to aggregate.

(c) The determination as to whether the amount in controversy is $100 or more is made by the administrative law judge (ALJ).

(d) In determining the amount in controversy under paragraph (b) of this section, the ALJ also makes the determination as to what constitutes ''similar or related services'' or ''common issues of law and fact.''

(e) When a civil action is filed by either an individual appellant or two or more appellants, the Secretary may assert that the aggregation principles contained in this subpart may be applied to determine the amount in controversy for judicial review ($1000).

(f) Notwithstanding the provisions of paragraphs (a)(1) and (b)(1) of this section, when payment is made for certain excluded services under §411.400 of this chapter or the liability of the beneficiary for those services is limited under §411.402 of this chapter, the amount in controversy is computed as the amount that would have been charged the beneficiary for the items or services in question, less any deductible and coinsurance amounts applicable in the particular case, had such expenses not been paid pursuant to §411.400 of this chapter or had such liability not been limited pursuant to §411.402 of this chapter.

(g) Under this subpart, an appellant may not combine part A and part B claims together to meet the requisite amount in controversy for a hearing. HMO, CMP and HCPP appellants under part 417 of this chapter may combine part A and part B claims together to meet the requisite amounts in controversy for a hearing.

[59 FR 12181, Mar. 16, 1994]

§405.745 Amount in controversy ascertained after reconsideration.

For the purpose of determining whether a party to a reconsidered determination is entitled to a hearing, the amount in controversey after the reconsideration action rather than the amount in controversy initially at issue shall be controlling.

[40 FR 1026, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.747 Dismissal of request for hearing; amount in controversy less than $100.

The ALJ shall, without holding a hearing, dismiss the request for hearing if the request for hearing plainly shows that less than $100 is in controversy. If a hearing is held and the ALJ finds that the amount in controversy is less than $100, the ALJ shall dismiss the request for hearing and will not rule on the substantive issues involved in the appeal.

[37 FR 5814, Mar. 23, 1972. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§ 405.750 Time period for reopening initial, revised, or reconsidered determinations and decisions or revised decisions of an ALJ or the Departmental Appeals Board (DAB); binding effect of determination and decisions.

(a) *Reopenings concerning applications and entitlement.* A determination, or decision, or revised determination or decision made by the SSA concerning any matter under §405.704(a), may be reopened and revised under 20 CFR 404.988 (Conditions for reopening).

(b) *Reopenings concerning a request for payment.* An initial, revised, or reconsidered determination of CMS, or a decision or revised decision of an ALJ or of the DAB, with respect to an individual's right concerning a request for payment under Medicare Part A, which is otherwise binding under 20 CFR 404.955 or 404.981 and §§ 405.708 or 405.717 of this subpart may be reopened:

(1) Within 12 months from the date of the notice of the initial or reconsidered determination to the party to such determination;

(2) After such 12-month period, but within 4 years after the date of the notice of the initial determination to the individual, upon establishment of good cause for reopening such determination or decision (see 20 CFR 404.988(b) and 404.989); or

(3) At any time, when:

(i) Such initial, revised, or reconsidered determination or such decision or revised decision is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting clerical error or error on the face of the evidence on which such determination or decision was based; or

(ii) Such initial, revised, or reconsidered determination or such decision or revised decision was procured by fraud or similar fault of the beneficiary or some other person.

[45 FR 73933, Nov. 7, 1980, as amended at 61 FR 32348, June 24, 1996; 62 FR 25853, 25855, May 12, 1997]

§ 405.753 Appeal of a categorization of a device.

(a) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under §405.203 is a national coverage decision under section 1862(a)(1) of the Act.

(b) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under §405.203 is an aspect of an initial determination that, under section 1862 of the Act, payment may not be made.

(c) In accordance with section 1869(b)(3)(A) of the Act, CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under §405.203 may not be reviewed by an administrative law judge.

[60 FR 48424, Sept. 19, 1995]

Subpart H—Appeals Under the Medicare Part B Program

AUTHORITY: Secs. 1102, 1842(b)(3)(C), 1869(b), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395u(b)(3)(C), 1395ff(b), and 1395hh).

SOURCE: 32 FR 18028, Dec. 16, 1967, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.801 Part B appeals—general description.

(a) The Medicare carrier makes an initial determination when a request for payment for Part B benefits is submitted. If an individual beneficiary is dissatisfied with the initial determination, he or she may request, and the carrier will perform, a review of the claim. Following the carrier's review determination, the beneficiary may obtain a carrier hearing if the amount remaining in controversy is at least $100.

The beneficiary is also entitled to a carrier hearing without the benefit of a review determination when the initial request for payment is not being acted upon with reasonable promptness (as defined in § 405.802). Following the carrier hearing, the beneficiary may obtain a hearing before an ALJ if the amount remaining in controversy is at least $500. If the beneficiary is dissatisfied with the decision of the ALJ, he or she may request the Departmental Appeals Board (DAB) to review the case. Following the action of the DAB, the beneficiary may file suit in Federal district court if the amount remaining in controversy is at least $1,000.

(b) The rights of a beneficiary under paragraph (a) of this section to appeal the carrier's initial determination are granted also to—

(1) A physician or supplier that furnishes services to a beneficiary and that accepts an assignment from the beneficiary, or

(2) A physician who meets the conditions of section 1842(l)(1)(A) of the Act pertaining to refund requirements for nonparticipating physicians who have not taken assignment on the claim(s) at issue.

(c) Procedures governing the determinations by SSA as to whether an individual has met basic Part B entitlement requirements are covered in subpart G of this part and 20 CFR part 404, subpart J. Subparts J and R of 20 CFR part 404 are also applicable to ALJ, DAB, and judicial review conducted under subpart H, except to the extent that specific provisions are contained in this subpart.

[62 FR 25853, May 12, 1997]

§ 405.802 Definitions.

As used in subpart H of this part, the term—

After receipt of the notice means 5 days after the date on the notice, unless it is shown that the notice was received earlier or later.

Appellant designates the beneficiary, assignee or other person or entity that has filed an appeal concerning a particular determination of benefits under Medicare part B. Designation as an appellant does not in itself convey standing to appeal the determination in question.

Assignee means a physician or supplier who furnishes services to a beneficiary under Medicare part B and who has accepted a valid assignment executed by the beneficiary.

Assignment means the transfer by the assignor of his or her claim for payment to the assignee in return for the latter's promise not to charge more for his or her services than the carrier finds to be the reasonable charge or other approved amount.

Assignor means a beneficiary under Medicare part B whose physician or supplier has taken assignment of a claim.

Carrier means an organization which has entered into a contract with the Secretary pursuant to section 1842 of the Act and which is authorized to make determinations with respect to part B of title XVIII of the Act. For purposes of this subpart, the term carrier also refers to an intermediary that has entered into a contract with the Secretary under section 1816 of the Act and is authorized to make determinations with respect to part B provider services, as specified in § 421.5(c) of this chapter.

Common issues of law and fact, with respect to the aggregation of claims by two or more appellants to meet the minimum amount in controversy needed for an ALJ hearing, occurs when the claims sought to be aggregated are denied or reduced for similar reasons and arise from a similar fact pattern material to the reason the claims are denied.

Delivery of similar or related services, with respect to the aggregation of claims by two or more physician/supplier appellants to meet the minimum amount in controversy needed for an ALJ hearing, means like or coordinated services or items provided to the same beneficiary by the appellants.

Representative means an individual meeting the conditions described in §§ 405.870 through 405.871.

With reasonable promptness means within a period of 60 consecutive days after the receipt by the carrier of a request for payment.

[59 FR 12182, Mar. 16, 1994, as amended at 62 FR 25853, May 12, 1997]

§ 405.803 Initial determination.

(a) Carriers make initial determinations regarding claims for benefits under Medicare Part B.

(b) An initial determination for purposes of this subpart includes determinations such as the following:

(1) Whether services furnished are covered.

(2) Whether the deductible has been met.

(3) Whether the receipted bill or other evidence of payment is acceptable.

(4) Whether the charges for services furnished are reasonable.

(5) If the services furnished to a beneficiary by a physician or a supplier pursuant to an assignment under § 424.55 of this chapter are not covered because they are determined to be not reasonable and necessary under § 411.15(k) of this chapter, whether the beneficiary, physician or supplier, or a physician who meets the requirements of § 411.408, knew or could reasonably have been expected to know at the time the services were furnished that the services were not covered.

(c) The following are not initial determinations for purposes of this subpart:

(1) Any issue or factor for which SSA or CMS has sole responsibility, for example, whether an independent laboratory meets the conditions for coverage of services; whether a Medicare overpayment claim should be compromised, or collection action terminated or suspended.

(2) Any issue or factor which relates to hospital insurance benefits under Medicare Part A.

[62 FR 25853, May 12, 1997]

§ 405.804 Notice of initial determination.

After a carrier has made an initial determination on a request for payment written notice of this determination shall be mailed to each party to the determination at his last known address. The notice of the determination shall inform each party to the determination of his right to have such determination reviewed.

§ 405.805 Parties to the initial determination.

The parties to the initial determination (see § 405.803) may be any party described in § 405.802.

[64 FR 52670, Sept. 30, 1999]

§ 405.806 Effect of Initial Determination.

The initial determination is binding upon all parties to the claim for benefits unless the determination is—

(a) Reviewed in accordance with §§ 405.810 through 405.812; or

(b) Revised as a result of a reopening in accordance with § 405.841.

[62 FR 25853, May 12, 1997]

§ 405.807 Request for review of initial determination.

(a) *General.* A party to an initial determination by a carrier, that is dissatisfied with the initial determination and wants to appeal the matter, may request that the carrier review the determination. The request for review by the party to an initial determination must clearly indicate that he or she is dissatisfied with the initial determination and wants to appeal the matter. The request for review does not constitute a waiver of the party's right to a hearing (under § 405.815) after the review.

(b) *Place and method of filing a request.* A request by a party for a carrier to review the initial determination may be made in one of the following ways:

(1) In writing and filed at an office of the carrier, SSA, or CMS.

(2) By telephone to the telephone number designated by the carrier as the appropriate number for the receipt of requests for review.

(c) *Time of filing request.* (1) The carrier must provide a period of 6 months after the date of the notice of the initial determination within which the party to the initial determination may request a review.

(2) The carrier may, upon request by the party, extend the period for requesting the review of the initial determination.

[64 FR 52670, Sept. 30, 1999]

§405.808 Parties to the review.

The parties to the review (as provided for in §405.807(a)) shall be the persons who were parties to the carrier's initial determination as described in §405.805, and any other party whose rights with respect to the particular claim being reviewed may be affected by such review.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§405.809 Opportunity to submit evidence.

The parties to the review (as provided for in §405.807(a)) shall have a reasonable opportunity to submit written evidence and contentions as to fact or law relative to the claim at issue.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§405.810 Review determination.

Subject to the provisions of §§405.807 through 405.809, the carrier shall review the claim in dispute and, upon the basis of the evidence of record, shall make a separate determination affirming or revising in whole or in part the findings and determination in question.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§405.811 Notice of review determination.

Written notice of the review determination is mailed to a party at his or her last known address. The review determination states the basis of the determination and advises the party of his or her right to a carrier hearing when the amount in controversy is $100 or more as determined in accordance with §405.817. The notice states the place and manner of requesting a carrier hearing as well as the time limit under which a hearing must be requested (see §405.821).

[59 FR 12182, Mar. 16, 1994]

§405.812 Effect of review determination.

The review determination is binding upon all parties to the review unless a carrier hearing decision is issued pursuant to a request for hearing made in accordance with §405.821 or is revised as a result of reopening in accordance with §405.841.

[59 FR 12182, Mar. 16, 1994, as amended at 62 FR 25855, May 12, 1997]

§405.815 Amount in controversy for carrier hearing, ALJ hearing and judicial review.

Any party designated in §405.822 is entitled to a carrier hearing after a review determination has been made by the carrier if the amount remaining in controversy is $100 or more and the party meets the requirements of §405.821 of this subpart. To be entitled to a hearing before an ALJ following the carrier hearing, the amount remaining in controversy must be $500 or more, and for judicial review following the ALJ hearing and Departmental Appeals Board Review, the amount remaining in controversy must be $1000 or more.

[59 FR 12182, Mar. 16, 1994, as amended at 61 FR 32348, June 24, 1996]

§405.817 Principles for determining amount in controversy.

(a) *Individual appellants.* For the purpose of determining whether an individual appellant meets the minimum amount in controversy needed for a carrier hearing ($100) or ALJ hearing ($500), the following rules apply:

(1) The amount in controversy is computed as the actual amount charged the individual for the items and services in question, less any amount for which payment has been made by the carrier and less any deductible and coinsurance amounts applicable in the particular case.

(2) A single beneficiary may aggregate claims from two or more physicians/suppliers to meet the $100 or $500 thresholds. A single physician/supplier may aggregate claims from two or more beneficiaries to meet the $100 or $500 threshold levels of appeal.

(3) In either of the circumstances specified in paragraph (a)(2) of this section, two or more claims may be aggregated by an individual appellant to meet the amount in controversy for a carrier hearing only if the claims have previously been reviewed and a request for hearing has been made within six months after the date of the review determination(s).

(4) In either of the circumstances specified in paragraph (a)(2) of this section, two or more claims may be aggregated by an individual appellant to meet the amount in controversy for an ALJ hearing only if the claims have previously been decided by a carrier hearing officer and a request for an ALJ hearing has been made within 60 days after receipt of the carrier hearing officer decision(s).

(5) When requesting a carrier hearing or an ALJ hearing, the appellant must specify in his or her appeal request the specific claims to be aggregated.

(b) *Two or more appellants.* As specified in this paragraph, under section 1869(b)(2) of the Act, two or more appellants may aggregate their claims together to meet the minimum amount in controversy needed for an ALJ hearing ($500). The right to aggregate under this statutory provision applies to claims for items and services furnished on or after January 1, 1987.

(1) The aggregate amount in controversy is computed as the actual amount charged the individual(s) for the items and services in question, less any amount for which payment has been made by the carrier and less any deductible and coinsurance amounts applicable in the particular case.

(2) In determining the amount in controversy, two or more appellants may aggregate their claims together under the following circumstances:

(i) Two or more beneficiaries may combine claims representing services from the same or different physician(s) or supplier(s) if the claims involve common issues of law and fact;

(ii) Two or more physicians/suppliers may combine their claims if the claims involve the delivery of similar or related services to the same beneficiary;

(iii) Two or more physicians/suppliers may combine their claims if the claims involve common issues of law and fact with respect to services furnished to two or more beneficiaries.

(iv) In any of the circumstances specified in paragraphs (b)(2)(i) through (b)(2)(iii) of this section, the claims may be aggregated only if the claims have previously been decided by a carrier hearing officer(s) and a request for ALJ hearing has been made within 60 days after receipt of the carrier hearing officer decision(s). Moreover, in a request for ALJ hearing, the appellants must specify the claims that they seek to aggregate.

(c) The determination as to whether the amount in controversy is $100 or more is made by the carrier hearing officer. The determination as to whether the amount in controversy is $500 or more is made by the ALJ.

(d) In determining the amount in controversy under paragraph (b) of this section, the ALJ will also make the determination as to what constitutes ''similar or related services'' or ''common issues of law and fact.''

(e) When a civil action is filed by either an individual appellant or two or more appellants, the Secretary may assert that the aggregation principles contained in this subpart may be applied to determine the amount in controversy for judicial review ($1000).

(f) Notwithstanding the provisions of paragraphs (a)(1) and (b)(1) of this section, when payment is made for certain excluded services under §411.400 of this chapter or the liability of the beneficiary for those services is limited under §411.402 of this chapter, the amount in controversy is computed as the amount that would have been charged the beneficiary for the items or services in question, less any deductible and coinsurance amounts applicable in the particular case, had such expenses not been paid under §411.400 of this chapter or had such liability not been limited under §411.402 of this chapter.

(g) Under this subpart, an appellant may not combine part A and part B claims together to meet the requisite amount in controversy for a carrier hearing or ALJ hearing. HMO, CMP and HCPP appellants under part 417 of this chapter may combine part A and part B claims together to meet the requisite amount in controversy for a hearing.

[59 FR 12182, Mar. 16, 1994]

§ 405.821 Request for carrier hearing.

(a) A request for a carrier hearing is any clear expression in writing by a claimant asking for a hearing to adjudicate a claim when not acted upon with reasonable promptness or by a party to a review determination who

states, in effect, that he or she is dissatisfied with the carrier's review determination and wants further opportunity to appeal the matter to the carrier.

(b) The hearing request must be filed at an office of the carrier or at an office of SSA or CMS.

(c) Except when a carrier hearing is held because the carrier did not act upon a claim with reasonable promptness, a party to the review determination may request a carrier hearing within six months after the date of the notice of the review determination. The carrier may, upon request by the party affected, extend the period for filing the request for hearing.

[59 FR 12183, Mar. 16, 1994, as amended at 62 FR 25855, May 12, 1997]

§ 405.822 Parties to a carrier hearing.

The parties to a hearing shall be the persons who were parties to the carrier's review determination (§ 405.808) which is in question. Any other person may be made a party if that person's rights with respect to supplementary medical insurance benefits may be prejudiced by the decision.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 12183, Mar. 16, 1994]

§ 405.823 Carrier hearing officer.

Any hearing provided for in this subpart shall be conducted by a hearing officer designated by the appropriate official of the carrier.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.824 Disqualification of carrier hearing officer.

A hearing officer shall not conduct a hearing in any case in which he is prejudiced or partial with respect to any party, or if he has any interest in the matter before him. Notice of any objection with respect to the hearing officer who will conduct the hearing shall be made by the objecting party at his earliest opportunity. The hearing officer shall consider such objection and shall, at his discretion, withdraw. If the hearing officer withdraws, the appropriate official of the carrier shall designate another hearing officer to conduct the hearing. If the hearing officer does not withdraw, the objecting party may present his objections to the carrier for consideration at any time prior to the issuance of a decision. The carrier shall review the request and take appropriate action. The fact that a hearing officer is an employee of the carrier may not serve as prima facie cause for disqualification.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 12183, Mar. 16, 1994]

§ 405.825 Location of carrier hearing.

(a) *Time and place.* The hearing officer shall fix a time and place for the hearing reasonably convenient to the requesting party and not inconsistent with the public interest.

(b) *Adjournment or postponement.* The hearing officer may, for a good and sufficient reason, fix a new time and/or place for the hearing; he may change the time and place for the hearing or adjourn the hearing on his own motion upon reasonable notification to the parties.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 12183, Mar. 16, 1994]

§ 405.826 Notice of carrier hearing.

The notice of hearing is to include notice of the time and place of the hearing; information as to the specific issues to be determined; and the matters on which findings will be made and conclusions will be reached. The notice is to contain sufficient information about the hearing procedure (including the party's right to representation) for effective preparation for the hearing.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 12183, Mar. 16, 1994]

§ 405.830 Conduct of the carrier hearing.

(a) *General.* Hearings shall be open to the parties and to such other persons as the hearing officer deems necessary and proper for the orderly and efficient conduct of the hearing. The hearing officer shall inquire fully into the matters at issue and shall receive in evidence the testimony of witnesses and

any documents which are relevant and material to such matters. The parties shall be provided an opportunity to enter any objection to the inclusion of any document. The order in which evidence and allegations shall be presented and the procedure at the hearing, except as this subpart otherwise expressly provides, shall be at the discretion of the hearing officer and of such nature as to afford the parties a proper hearing.

(b) *Evidence.* Evidence may be received at the hearing even though inadmissible under rules of evidence applicable to court procedures.

(c) *Witnesses.* The hearing officer may examine the witnesses and shall allow the parties or their representatives to do so. If the hearing officer conducts the examination of a witness, he may allow the parties to suggest matters upon which they desire the witness to be questioned, and the hearing officer shall question the witness with respect to such matters if they are relevant and material to any issue pending for decision before him.

(d) *Oral argument and written allegations.* The parties, upon their request shall be allowed a reasonable time for the presentation of oral argument or for the filing of briefs or other written statements or allegations of facts or law.

(e) *Consolidated issues.* When one or more new issues are raised at any time after a request for hearing has been made, but before the mailing of notice of the decision, the hearing officer may, at his discretion, consider the issues along with the other issues pending before him on the same request for hearing.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 12183, Mar. 16, 1994]

§ 405.831 Waiver of right to appear at carrier hearing and present evidence.

If all parties waive their right to appear before the hearing officer and present evidence and contentions personally or by representative, it shall not be necessary for the hearing officer to give notice of or conduct a formal hearing as provided in §§ 405.825 through 405.830. A waiver of the right to appear is to be in writing and filed with the hearing officer or the carrier. Such waiver may be withdrawn by a party at any time prior to the mailing of notice of the decision in the case. Even though all of the parties have filed a waiver of the right to appear and present evidence and contentions at a hearing before the hearing officer, the hearing officer may, nevertheless, give notice of a time and place and conduct a hearing as provided in §§ 405.825 through 405.830, if he believes that the personal appearance and testimony of the party or parties would assist him to ascertain the facts at issue in the case. For purposes of this section, failure of the parties to appear shall not be cause for a finding of abandonment and the hearing officer shall make his decision on the basis of all evidence adduced.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§ 405.832 Dismissal of request for carrier hearing.

(a) *By application of party.* With the approval of the hearing officer, a request for a hearing may be withdrawn or dismissed at any time prior to the mailing of notice of the decision upon the application of the party or parties filing the request for such hearing. A party may request a dismissal by filing a written notice of such request with the carrier, the hearing officer or orally stating such request at the hearing. The dismissal of a request for hearing shall be binding unless vacated (see paragraph (d) of this section).

(b) *Dismissal by abandonment of party.* A hearing officer may dismiss a request for hearing upon abandonment by the party or parties who filed the request. A party shall be deemed to have abandoned a request for hearing, other than where personal appearance is waived in accordance with § 405.831, if neither the party nor his representative appears at the time and place fixed for the hearing and within 10 days after the mailing of a notice to him by the hearing officer to show cause, such party does not show good and sufficient cause for such failure to appear and failure to notify the hearing officer prior to the time

fixed for hearing that he cannot appear.

(c) *Dismissal for cause.* The hearing officer may, on his own motion, dismiss a hearing request, either entirely or as to any stated issue, under either of the following circumstances:

(1) Where the party requesting a hearing is not a proper party under § 405.822 or does not otherwise have a right to a hearing under section 1842(b)(3)(C) of the Act; or

(2) Where the party who filed the hearing request dies and there is no information before the hearing officer showing that an individual who is not a party may be prejudiced by the carrier's determination.

(d) *Dismissal without prejudice.* The hearing officer may on his own motion dismiss without prejudice a hearing request where the amount in controversy is less than $100.

(e) *Vacation of dismissal.* A hearing officer may, on request of a party and for good and sufficient cause shown, vacate any dismissal of a request for hearing at any time within 6 months from the date of mailing notice of the dismissal to the party requesting the hearing at his last known address.

[32 FR 18028, Dec. 16, 1967, as amended at 39 FR 12098, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 12183, Mar. 16, 1994; 62 FR 25855, May 12, 1997]

§ 405.833 Record of carrier hearing.

A complete record of the proceedings at the carrier hearing is made. The testimony is transcribed and copies of other documentary evidence are reproduced in any case when directed by the hearing officer, the carrier, or CMS. The record will also be transcribed and reproduced at the request of any party to the hearing provided the requesting party bears the cost.

[62 FR 25853, May 12, 1997]

§ 405.834 Carrier hearing officer's decision.

(a) As soon as practicable after the close of a carrier hearing, the carrier hearing officer issues a decision in the case based upon the evidence presented at the hearing or otherwise included in the hearing record. The decision is issued as a written notice to the parties and contains—

(1) Findings of fact,

(2) A statement of reasons, and

(3) Notification to the parties of their right to an ALJ hearing when the amount remaining in controversy is at least $500.

(b) A copy of the decision is mailed to the parties to the hearing at their last known addresses.

[62 FR 25854, May 12, 1997]

§ 405.835 Effect of carrier hearing officer's decision.

The carrier hearing officer's decision is binding upon all parties to the hearing unless—

(a) A request for an ALJ hearing is filed in accordance with § 405.855, or

(b) The decision is revised in accordance with § 405.841.

[62 FR 25854, May 12, 1997]

§ 405.836 Authority of the carrier hearing officer.

The carrier hearing officer, in adjudicating Medicare Part B claims, complies with all of the provisions of, and regulations issued under, title XVIII of the Act, as well as with CMS Rulings, national coverage decisions, and other policy statements, instructions, and guides issued by CMS.

[62 FR 25854, May 12, 1997]

§ 405.841 Reopening initial or review determination of the carrier, and decision of a carrier hearing officer.

An initial or review determination of a carrier or a decision of a hearing officer may be reopened by such carrier or hearing officer:

(a) Within 12 months from the date of the notice of such initial or review determination or decision to the party to such determination or decision; or

(b) After such 12-month period, but within 4 years from the date of the notice of the initial determination to the party to such determination, upon establishment of good cause for reopening such determination or decision (see 20 CFR 404.988(b) and 404.989); or

(c) At any time, when:

(1) Such initial or review determination or decision was procured by fraud or similar fault of the beneficiary or some other person, or

(2) Such initial or review determination or decision is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error or error on the face of the evidence on which such determination or decision was based.

[39 FR 12098, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 12183, Mar. 16, 1994; 62 FR 25855, May 12, 1997]

§ 405.842 Notice of reopening and revision.

(a) *Notice.* When any determination or decision is reopened as provided in § 405.841, notice of such reopening shall be mailed to the parties to such determination or decision at their last known addresses. A notice of revision following a reopening of a decision, shall be mailed to the parties and shall state the basis for the revised determination or decision.

(b) *Effect of revised determination.* The revision of a determination (see § 405.841) shall be binding upon all parties thereto unless a party files a written request for a hearing with respect to a revised determination when the amount in controversy is $100 or more.

[32 FR 18028, Dec. 16, 1967, as amended at 39 FR 12098, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977; 62 FR 25855, May 12, 1997]

§ 405.850 Change of ruling or legal precedent.

Change of a legal interpretation or administrative ruling upon which a determination or decision was made shall not be considered as good and sufficient reason for reopening the determination or decision.

§ 405.853 Expedited appeals process.

(a) *Conditions for use of expedited appeals process (EAP).* A party may use the EAP set forth in § 405.718 of this chapter to request court review in place of the ALJ hearing or Departmental Appeals Board (DAB) review if the following conditions are met:

(1) The carrier hearing officer has made a decision; an ALJ has made a hearing decision; or DAB review has been requested, but a final decision has not been issued.

(2) The filing entity is a party referred to in § 405.718(d) of this chapter.

(3) The party has filed a request for an ALJ hearing in accordance with § 405.855, or DAB review in accordance with 20 CFR 404.968.

(4) The amount remaining in controversy is $1,000 or more.

(5) If there is more than one party to the hearing decision, each party concurs, in writing, with the request for an EAP.

(b) *Content of the request for EAP.* The request for an EAP:

(1) Alleges that there are no material issues of fact in dispute; and

(2) Asserts that the only factor precluding a decision favorable to the party is a statutory provision that is unconstitutional or a regulation, national coverage decision under section 1862(a)(1) of the Act, or CMS Ruling that is invalid.

[62 FR 25854, May 12, 1997]

§ 405.855 ALJ hearing.

(a) *Right to hearing.* A party to the carrier hearing has a right to a hearing before an ALJ if—

(1) The party files a written request for an ALJ hearing within 60 days after receipt of the notice of the carrier hearing decision; and

(2) The amount remaining in controversy is $500 or more.

(b) *Place of filing hearing request.* The request for an ALJ hearing must be made in writing and filed with the carrier that issued the decision, a Social Security office, or, in the case of a qualified railroad retirement beneficiary, an office of the Railroad Retirement Board.

(c) *Effect of ALJ hearing decision.* (1) An ALJ's decision is binding on all parties to the hearing unless—

(i) The DAB reviews the ALJ decision;

(ii) The DAB does not review the ALJ decision, and the party requests judicial review;

(iii) The decision is revised by the DAB or an ALJ in accordance with the provisions of § 405.750 of this chapter; or

(iv) The expedited appeals process is used.

[62 FR 25854, May 12, 1997]

§ 405.856 Departmental Appeals Board (DAB) review.

Regulations beginning at 20 CFR 404.967 regarding SSA Appeals Council Review are applicable to DAB review of matters addressed by this subpart.

[62 FR 25854, May 12, 1997]

§ 405.857 Court review.

(a) *General rule.* To the extent authorized by sections 1869, 1876(c)(5)(B), and 1879(d) of the Act, a party to a DAB decision, or an ALJ decision if the DAB does not review the ALJ's decision, may obtain a court review if the amount remaining in controversy is $1,000 or more. A party may obtain court review by filing a civil action in a district court of the United States in accordance with the provisions of section 205(g) of the Act. The filing procedure is set forth in 20 CFR 422.210.

(b) *Prohibition against court review of certain Part B regulations or instructions.* Under section 1869(b)(4) of the Act, a court may not review a regulation or instruction that relates to a method of payment under Part B if the regulation was promulgated, or the instruction issued, before January 1, 1981.

[62 FR 25854, May 12, 1997]

§ 405.860 Review of a national coverage determination (NCD).

(a) *General rule.* (1) An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under title XVIII of the Act.

(2) An NCD does not include a determination of what code, if any, is assigned to a particular item or service covered under title XVIII or a determination for the amount of payment made for a particular item or service.

(3) NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act.

(4) An NCD is binding on all Medicare carriers, fiscal intermediaries, QIOs, HMOs, CMPs, HCPPs, the Medicare Appeals Council, and ALJs.

(b) *Review by ALJ.* (1) An ALJ may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD is applied correctly to the claim.

(c) *Review by Court.* For initial determinations and NCD challenges under section 1862(a)(1) of the Act, arising before October 1, 2002, a court's review of an NCD is limited to whether the record is incomplete or otherwise lacks adequate information to support the validity of the decision, unless the case is remanded to the Secretary to supplement the record regarding the NCD. In these cases, the court may not invalidate an NCD except upon review of the supplemental record.

[68 FR 63716, Nov. 7, 2003]

§ 405.870 Appointment of representative.

A party to an initial determination, informal review or hearing as provided in §§ 405.803 through 405.934, may appoint as his representative in any such proceeding any person qualified under § 405.871. Where the representative is an attorney, in the absence of information to the contrary, his representation that he has such authority shall be accepted as evidence of the attorney's authority to represent a party.

§ 405.871 Qualifications of representatives.

Any individual may be appointed to act as representative in accordance with § 405.870, unless he is disqualified or suspended from acting as a representative in proceedings before the SSA or the CMS or unless otherwise prohibited by law.

[39 FR 12098, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§ 405.872 Authority of representatives.

A representative, appointed and qualified as provided in §§ 405.870 and 405.871, may make or give, on behalf of the party he represents, any request or notice relative to any proceeding before the carrier including review and hearing. A representative shall be entitled to present evidence and allegations as to facts and law in any proceeding affecting the party he represents and to obtain information with respect to the claim of such party to the same extent as such party. Notice

to any party or any action, determination, or decision, or request to any party for the production of evidence, shall be sent to the representative of such party.

§ 405.874 Appeals of carrier decisions that supplier standards are not met.

(a) An entity serving as a National Supplier Clearinghouse must act promptly to determine if any entity submitting a request for a billing number as a Medicare supplier of part B items meets the standards set forth in part 424. Effective July 1, 1993, the National Supplier Clearinghouse must accept, reject or request additional information within 15 days of the receipt of an enrollment application.

(b) If the National Supplier Clearinghouse disallows an entity's request for a billing number or revokes, with the concurrence of CMS, an entity's billing number, the National Supplier Clearinghouse notifies the entity by certified mail. Revocation is effective 15 days after the National Supplier Clearinghouse mails notice of its determination. The carrier disallows payment for items furnished by the supplier beginning with that effective date. The notice must inform the entity of the reason for the rejection or revocation, its right to appeal, the date by which it must file that appeal (90 days after the postmark of the notice) and the address to which the appeal must be sent in writing.

(c) A fair hearing officer not involved in the original determination to disallow an entity's request for a billing number, or to revoke an entity's billing number, must schedule a hearing to be held within one week of receipt of an appeal, or later at the request of the entity. Both the entity and carrier may offer evidence. The hearing officer issues notice of his/her decision within 2 weeks of the hearing. The notice is sent by certified letter to CMS, the carrier, and the appealing entity. This notice must include information about the supplier's further right to appeal, the carrier's right to appeal, the date by which the appeal must be filed (90 days after the postmark of the notice) and the address to which the appeals must be sent in writing. Either the carrier or entity may appeal the hearings officer's decision to CMS.

(d) A CMS official, designated by the Administrator of CMS, must make an appeal decision based on the evidence presented to the fair hearing officer and his or her decision. The CMS official requests any additional information he or she deems necessary from either the carrier or the entity within two weeks of receipt by the CMS of the appeal. Notice of the CMS official's decision—

(1) Is issued within two weeks of when the last information is received is received by the CMS official, or four weeks of when the information is requested, whichever is shorter, unless the party appealing the fair hearing decision requests a delay;

(2) Is sent by the CMS official by certified mail to both the carrier and the entity; and

(3) Contains information on any further appeals the entity and carrier may have.

(e) A billing number is not issued, or remains revoked, and payment is not made, for items or services furnished by any entity which a carrier determines does not qualify for a billing number, until the carrier (upon reapplication of the entity), a fair hearing officer, or a CMS official designated to hear such appeals, determines that the entity qualifies for a billing number. Any claims for items or services furnished after revocation of the supplier's billing number and submitted by the entity during the appeals period are held and not processed, i.e., are neither approved, denied or developed, until all administrative appeals have been exhausted. If an entity is determined not to have qualified for a billing number in one period but to have qualified in another, the carrier pays for claims for items sold or rented to beneficiaries during the period the entity qualified as a supplier. If there is evidence of an overpayment, see subpart C of part 405 of this Chapter.

(f) A billing number may be reinstated after revocation when an entity completes a corrective action plan, to which CMS has agreed, and provided sufficient assurance of its intent to

comply fully with the supplier standards.

[57 FR 27305, June 18, 1992]

§ 405.877 Appeal of a categorization of a device.

(a) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is a national coverage decision under section 1862(a)(1) of the Act.

(b) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is an aspect of an initial determination that, under section 1862 of the Act, payment may not be made.

(c) In accordance with section 1869(b)(3)(A) of the Act, CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 may not be reviewed by an administrative law judge.

[60 FR 48424, Sept. 19, 1995]

Subpart I—Determinations, Redeterminations, Reconsiderations, and Appeals Under Original Medicare (Part A and Part B)

SOURCE: 70 FR 11472, Mar. 8, 2005, unless otherwise noted.

§ 405.900 Basis and scope.

(a) *Statutory basis.* This subpart is based on the provisions of sections 1869 (a) through (e) and (g) of the Act.

(b) *Scope.* This subpart establishes the requirements for appeals of initial determinations for benefits under Part A or Part B of Medicare, including the following:

(1) The initial determination of whether an individual is entitled to benefits under Part A or Part B. (Regulations governing reconsiderations of these initial determinations are at 20 CFR, part 404, subpart J).

(2) The initial determination of the amount of benefits available to an individual under Part A or Part B.

(3) Any other initial determination relating to a claim for benefits under Part A or Part B, including an initial determination made by a quality improvement organization under section 1154(a)(2) of the Act or by an entity under contract with the Secretary (other than a contract under section 1852 of the Act) to administer provisions of titles XVIII or XI of the Act.

§ 405.902 Definitions.

For the purposes of this subpart, the term—

ALJ means an Administrative Law Judge of the Department of Health and Human Services.

Appellant means the beneficiary, assignee or other person or entity that has filed and pursued an appeal concerning a particular initial determination. Designation as an appellant does not in itself convey standing to appeal the determination in question.

Appointed representative means an individual appointed by a party to represent the party in a Medicare claim or claim appeal.

Assignee means:

(1) A supplier that furnishes items or services to a beneficiary and has accepted a valid assignment of a claim or

(2) A provider or supplier that furnishes items or services to a beneficiary, who is not already a party, and has accepted a valid assignment of the right to appeal a claim executed by the beneficiary.

Assignment of a claim means the transfer by a beneficiary of his or her claim for payment to the supplier in return for the latter's promise not to charge more for his or her services than what the carrier finds to be the Medicare-approved amount, as provided in § 424.55 and § 424.56 of this chapter.

Assignment of appeal rights means the transfer by a beneficiary of his or her right to appeal under this subpart to a provider or supplier who is not already a party, as provided in section 1869(b)(1)(C) of the Act.

Assignor means a beneficiary whose provider of services or supplier has taken assignment of a claim or an appeal of a claim.

Authorized representative means an individual authorized under State or other applicable law to act on behalf of a beneficiary or other party involved in

the appeal. The authorized representative will have all of the rights and responsibilities of a beneficiary or party, as applicable, throughout the appeals process.

Beneficiary means an individual who is enrolled to receive benefits under Medicare Part A or Part B.

Carrier means an organization that has entered into a contract with the Secretary in accordance to section 1842 of the Act and is authorized to make determinations for Part B of title XVIII of the Act.

Clean claim means a claim that has no defect or impropriety (including any lack of required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under title XVIII within the time periods specified in sections 1816(c) and 1842(c) of the Act.

Family member means for purposes of the QIC reconsideration panel under §405.968 the following persons as they relate to the physician or healthcare provider.

(1) The spouse (other than a spouse who is legally separated from the physician or health care professional under a decree of divorce or separate maintenance);

(2) Children (including stepchildren and legally adopted children);

(3) Grandchildren;

(4) Parents; and

(5) Grandparents.

Fiscal Intermediary means an organization that has entered into a contract with CMS in accordance with section 1816 of the Act and is authorized to make determinations and payments for Part A of title XVIII of the Act, and Part B provider services as specified in §421.5(c) of this chapter.

MAC stands for the Medicare Appeals Council within the Departmental Appeals Board of the U.S. Department of Health and Human Services.

Party means an individual or entity listed in §405.906 that has standing to appeal an initial determination and/or a subsequent administrative appeal determination.

Provider means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice that has in effect an agreement to participate in Medicare, or clinic, rehabilitation agency, or public health agency that has in effect a similar agreement, but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

Qualified Independent Contractor (QIC) means an entity which contracts with the Secretary in accordance with section 1869 of the Act to perform reconsiderations under §405.960 through §405.978.

Quality Improvement Organization (QIO) means an entity that contracts with the Secretary in accordance with sections 1152 and 1153 of the Act and 42 CFR subchapter F, to perform the functions described in section 1154 of the Act and 42 CFR subchapter F, including expedited determinations as described in §405.1200 through §405.1208.

Reliable evidence means evidence that is relevant, credible, and material.

Remand means to vacate a lower level appeal decision, or a portion of the decision, and return the case, or a portion of the case, to that level for a new decision.

Similar fault means to obtain, retain, convert, seek, or receive Medicare funds to which a person knows or should reasonably be expected to know that he or she or another for whose benefit Medicare funds are obtained, retained, converted, sought, or received is not legally entitled. This includes, but is not limited to, a failure to demonstrate that he or she filed a proper claim as defined in part 411 of this chapter.

Supplier means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under Medicare.

Vacate means to set aside a previous action.

§405.904 Medicare initial determinations, redeterminations and appeals: General description.

(a) *General overview*—(1) *Entitlement appeals.* The SSA makes an initial determination on an application for

Medicare benefits and/or entitlement of an individual to receive Medicare benefits. A beneficiary who is dissatisfied with the initial determination may request, and SSA will perform, a reconsideration in accordance with 20 CFR part 404, subpart J if the requirements for obtaining a reconsideration are met. Following the reconsideration, the beneficiary may request a hearing before an Administrative Law Judge (ALJ) under this subpart (42 CFR part 405, subpart I). If the beneficiary obtains a hearing before an ALJ and is dissatisfied with the decision of the ALJ, he or she may request the Medicare Appeals Council (MAC) to review the case. Following the action of the MAC, the beneficiary may be entitled to file suit in Federal district court.

(2) *Claim appeals.* The Medicare contractor makes an initial determination when a claim for Medicare benefits under Part A or Part B is submitted. A beneficiary who is dissatisfied with the initial determination may request that the contractor perform a redetermination of the claim if the requirements for obtaining a redetermination are met. Following the contractor's redetermination, the beneficiary may request, and the Qualified Independent Contractor (QIC) will perform, a reconsideration of the claim if the requirements for obtaining a reconsideration are met. Following the reconsideration, the beneficiary may request, and the ALJ will conduct a hearing if the amount remaining in controversy and other requirements for an ALJ hearing are met. If the beneficiary is dissatisfied with the decision of the ALJ, he or she may request the MAC to review the case. If the MAC reviews the case and issues a decision, and the beneficiary is dissatisfied with the decision, the beneficiary may file suit in Federal district court if the amount remaining in controversy and the other requirements for judicial review are met.

(b) *Non-beneficiary appellants.* In general, the procedures described in paragraph (a) of this section are also available to parties other than beneficiaries either directly or through a representative acting on a party's behalf, consistent with the requirements of this subpart I. A provider generally has the right to judicial review only as provided under section 1879(d) of the Act; that is, when a determination involves a finding that services are not covered because—

(1) They were custodial care (see §411.15(g) of this chapter); they were not reasonable and necessary (see §411.15(k) of this chapter); they did not qualify as covered home health services because the beneficiary was not confined to the home or did not need skilled nursing care on an intermittent basis (see §409.42(a) and (c)(1) of this chapter); or they were hospice services provided to a non-terminally ill individual (see §418.22 of this chapter); and

(2) Either the provider or the beneficiary, or both, knew or could reasonably be expected to know that those services were not covered under Medicare.

§405.906 Parties to the initial determinations, redeterminations, reconsiderations, hearings and reviews.

(a) *Parties to the initial determination.* The parties to the initial determination are the following individuals and entities:

(1) A beneficiary who files a claim for payment under Medicare Part A or Part B or has had a claim for payment filed on his or her behalf, or in the case of a deceased beneficiary, when there is no estate, any person obligated to make or entitled to receive payment in accordance with part 424, subpart E of this chapter. Payment by a third party payer does not entitle that entity to party status.

(2) A supplier who has accepted assignment for items or services furnished to a beneficiary that are at issue in the claim.

(3) A provider of services who files a claim for items or services furnished to a beneficiary.

(b) *Parties to the redetermination, reconsideration, hearing and MAC.* The parties to the redetermination, reconsideration, hearing, and MAC review are—

(1) The parties to the initial determination in accordance with paragraph (a) of this section, except under paragraph (a)(1) of this section where a beneficiary has assigned appeal rights under §405.912;

(2) A State agency in accordance with § 405.908;

(3) A provider or supplier that has accepted an assignment of appeal rights from the beneficiary according to § 405.912;

(4) A non-participating physician not billing on an assigned basis who, in accordance with section 1842(l) of the Act, may be liable to refund monies collected for services furnished to the beneficiary because those services were denied on the basis of section 1862(a)(1) of the Act; and

(5) A non-participating supplier not billing on an assigned basis who, in accordance with sections 1834(a)(18) and 1834(j)(4) of the Act, may be liable to refund monies collected for items furnished to the beneficiary.

(c) *Appeals by providers and suppliers when there is no other party available.* If a provider or supplier is not already a party to the proceeding in accordance with paragraphs (a) and (b) of this section, a provider of services or supplier may appeal an initial determination relating to services it rendered to a beneficiary who subsequently dies if there is no other party available to appeal the determination.

§ 405.908 Medicaid State agencies.

When a beneficiary is enrolled to receive benefits under both Medicare and Medicaid, the Medicaid State agency may file a request for an appeal with respect to a claim for items or services furnished to a dually eligible beneficiary only for services for which the Medicaid State agency has made payment, or for which it may be liable. A Medicaid State agency is considered a party only when it files a timely redetermination request with respect to a claim for items or services furnished to a beneficiary in accordance with 42 CFR parts 940 through 958. If a State agency files a request for redetermination, it may retain party status at the QIC, ALJ, MAC, and judicial review levels.

§ 405.910 Appointed representatives.

(a) *Scope of representation.* An appointed representative may act on behalf of an individual or entity in exercising his or her right to an initial determination or appeal. Appointed representatives do not have party status and may take action only on behalf of the individual or entity that they represent.

(b) *Persons not qualified.* A party may not name as an appointed representative, an individual who is disqualified, suspended, or otherwise prohibited by law from acting as a representative in any proceedings before DHHS, or in entitlement appeals, before SSA.

(c) *Completing a valid appointment.* For purposes of this subpart, an appointment of representation must:

(1) Be in writing and signed and dated by both the party and individual agreeing to be the representative;

(2) Provide a statement appointing the representative to act on behalf of the party, and in the case of a beneficiary, authorizing the adjudicator to release identifiable health information to the appointed representative.

(3) Include a written explanation of the purpose and scope of the representation;

(4) Contain both the party's and appointed representative's name, phone number, and address;

(5) Identify the beneficiary's Medicare health insurance claim number;

(6) Include the appointed representative's professional status or relationship to the party;

(7) Be filed with the entity processing the party's initial determination or appeal.

(d) *Curing a defective appointment of representative.* (1) If any one of the seven elements named in paragraph (c) of this section is missing from the appointment, the adjudicator should contact the party and provide a description of the missing documentation or information.

(2) Unless the defect is cured, the prospective appointed representative lacks the authority to act on behalf of the party, and is not entitled to obtain or receive any information related to the appeal, including the appeal decision.

(e) *Duration of appointment.* (1) Unless revoked, an appointment is considered valid for 1 year from the date that the Appointment of Representative (AOR) form or other conforming written instrument contains the signatures of both the party and the appointed representative.

(2) To initiate an appeal within the 1-year time frame, the representative must file a copy of the AOR form, or other conforming written instrument, with the appeal request. Unless revoked, the representation is valid for the duration of an individual's appeal of an initial determination.

(3) For an initial determination of a Medicare Secondary Payer recovery claim, an appointment signed in connection with the party's efforts to make a claim for third party payment is valid from the date that appointment is signed for the duration of any subsequent appeal, unless the appointment is specifically revoked.

(f) *Appointed representative fees*—(1) *General rule.* An appointed representative for a beneficiary who wishes to charge a fee for services rendered in connection with an appeal before the Secretary must obtain approval of the fee from the Secretary. Services rendered below the ALJ level are not considered proceedings before the Secretary.

(2) *No fees or costs against trust funds.* No award of attorney or any other representative's fees or any costs in connection with an appeal may be made against the Medicare trust funds.

(3) *Special rules for providers and suppliers.* A provider or supplier that furnished the items or services to a beneficiary that are the subject of the appeal may represent that beneficiary in an appeal under this subpart, but the provider or supplier may not charge the beneficiary any fee associated with the representation. If a provider or supplier furnishes services or items to a beneficiary, the provider or supplier may not represent the beneficiary on the issues described in section 1879(a)(2) of the Act, unless the provider or supplier waives the right to payment from the beneficiary for the services or items involved in the appeal.

(4) *Special rules for purposes of third party payment.* The Secretary does not review fee arrangements made by a beneficiary for purposes of making a claim for third party payment (as defined in 42 CFR 411.21) even though the representation may ultimately include representation for a Medicare Secondary Payer recovery claim.

(5) *Reasonableness of representative fees.* In determining the reasonableness of a representative's fee, the Secretary will not apply the test specified in sections 206(a)(2) and (a)(3) of the Act.

(g) *Responsibilities of an appointed representative.* (1) An appointed representative has an affirmative duty to—

(i) Inform the party of the scope and responsibilities of the representation;

(ii) Inform the party of the status of the appeal and the results of actions taken on behalf of the party, including, but not limited to, notification of appeal determinations, decisions, and further appeal rights;

(iii) Disclose to a beneficiary any financial risk and liability of a non-assigned claim that the beneficiary may have;

(iv) Not act contrary to the interest of the party; and

(v) Comply with all laws and CMS regulations, CMS Rulings, and instructions.

(2) An appeal request filed by a provider or supplier described in paragraph (f)(3) of this section must also include a statement signed by the provider or supplier stating that no financial liability is imposed on the beneficiary in connection with that representation. If applicable, the appeal request must also include a signed statement that the provider or supplier waives the right to payment from the beneficiary for services or items regarding issues described in section 1879(a)(2) of the Act.

(h) *Authority of an appointed representative.* An appointed representative may, on behalf of the party—

(1) Obtain appeals information about the claim to the same extent as the party;

(2) Submit evidence;

(3) Make statements about facts and law; and

(4) Make any request, or give, or receive, any notice about the appeal proceedings.

(i) *Notice or request to an appointed representative*—(1) *Initial determinations.* When a contractor takes an action or issues an initial determination, it sends the action or notice to the party.

(2) *Appeals.* When a contractor, QIC, ALJ, or the MAC takes an action or

issues a redetermination, reconsideration, or appeal decision, in connection with an initial determination, it sends notice of the action to the appointed representative.

(3) The contractor, QIC, ALJ or MAC sends any requests for information or evidence regarding a claim that is appealed to the appointed representative. The contractor sends any requests for information or evidence regarding an initial determination to the party.

(4) For initial determinations and appeals involving Medicare Secondary Payer recovery claims, the adjudicator sends notices and requests to both the beneficiary and the appointed representative.

(j) *Effect of notice or request to an appointed representative.* A notice or request sent to the appointed representative has the same force and effect as if was sent to the party.

(k) *Information available to the appointed representative.* An appointed representative may obtain any and all appeals information applicable to the claim at issue that is available to the party.

(l) *Delegation of appointment by appointed representative.* An appointed representative may not designate another individual to act as the appointed representative of the party unless—

(1) The appointed representative provides written notice to the party of the appointed representative's intent to delegate to another individual. The notice must include:

(i) The name of the designee; and

(ii) The designee's acceptance to be obligated and comply with the requirements of representation under this subpart.

(2) The party accepts the designation as evidenced by a written statement signed by the party. This signed statement is not required when the appointed representative and designee are attorneys in the same law firm or organization.

(m) *Revoking the appointment of representative.* (1) A party may revoke an appointment of representative without cause at any time.

(2) *Revocation.* Revocation is not effective until the adjudicator receives a signed, written statement from the party.

(3) *Death of the party.* (i) The death of a party terminates the authority of the appointed representative, except as specified in paragraph (m)(3)(ii) of this section.

(ii) A party's death does not terminate an appeal that is in progress if another individual or entity may be entitled to receive or obligated to make payment for the items or services that are the subject of the appeal. The appointment of representative remains in effect for the duration of the appeal except for MSP recovery claims.

§ 405.912 Assignment of appeal rights.

(a) *Who may be an assignee.* Only a provider, or supplier that—

(1) Is not a party to the initial determination as defined in § 405.906; and

(2) Furnished an item or service to the beneficiary may seek assignment of appeal rights from the beneficiary for that item or service.

(b) *Who may not be an assignee.* An individual or entity who is not a provider or supplier may not be an assignee. A provider or supplier that furnishes an item or service to a beneficiary may not seek assignment for that item or service when considered a party to the initial determination as defined in § 405.906.

(c) *Requirements for a valid assignment of appeal right.* The assignment of appeal rights must—

(1) Be executed using a CMS standard form;

(2) Be in writing and signed by both the beneficiary assigning his or her appeal rights and by the assignee;

(3) Indicate the item or service for which the assignment of appeal rights is authorized;

(4) Contain a waiver of the assignee's right to collect payment from the assignor for the specific item or service that are the subject of the appeal except as set forth in paragraph (d)(2) of this section; and

(5) Be submitted at the same time the request for redetermination or other appeal is filed.

(d) *Waiver of right to collect payment.* (1) Except as specified in paragraph (d)(2) of this section, the assignee must waive the right to collect payment for

the item or service for which the assignment of appeal rights is made. If the assignment is revoked under paragraph (g)(2) or (g)(3) of this section, the waiver of the right to collect payment nevertheless remains valid. A waiver of the right to collect payment remains in effect regardless of the outcome of the appeal decision.

(2) The assignee is not prohibited from recovering payment associated with coinsurance or deductibles or when an advance beneficiary notice is properly executed.

(e) *Duration of a valid assignment of appeal rights.* Unless revoked, the assignment of appeal rights is valid for all administrative and judicial review associated with the item or service as indicated on the standard CMS form, even in the event of the death of the assignor.

(f) *Rights of the assignee.* When a valid assignment of appeal rights is executed, the assignor transfers all appeal rights involving the particular item or service to the assignee. These include, but are not limited to—

(1) Obtaining information about the claim to the same extent as the assignor;

(2) Submitting evidence;

(3) Making statements about facts or law; and

(4) Making any request, or giving, or receiving any notice about appeal proceedings.

(g) *Revocation of assignment.* When an assignment of appeal rights is revoked, the rights to appeal revert to the assignor. An assignment of appeal rights may be revoked in any of the following ways:

(1) *In writing by the assignor.* The revocation of assignment must be delivered to the adjudicator and the assignee, and is effective on the date of receipt by the adjudicator.

(2) By abandonment if the assignee does not file an appeal of an unfavorable decision.

(3) By act or omission by the assignee that is determined by an adjudicator to be contrary to the financial interests of the assignor.

(h) *Responsibilities of the assignee.* Once the assignee files an appeal, the assignee becomes a party to the appeal. The assignee must meet all requirements for appeals that apply to any other party.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005]

INITIAL DETERMINATIONS

§ 405.920 Initial determinations.

After a claim is filed with the appropriate contractor in the manner and form described in subpart C of part 424 of this chapter, the contractor must—

(a) Determine if the items and services furnished are covered or otherwise reimbursable under title XVIII of the Act;

(b) Determine any amounts payable and make payment accordingly; and

(c) Notify the parties to the initial determination of the determination in accordance with § 405.921.

§ 405.921 Notice of initial determination.

(a) *Notice of initial determination sent to the beneficiary.* (1) The notice must be written in a manner calculated to be understood by the beneficiary, and sent to the last known address of the beneficiary;

(2) *Content of the notice.* The notice of initial determination must contain—

(i) The reasons for the determination, including whether a local medical review policy, a local coverage determination, or national coverage determination was applied;

(ii) The procedures for obtaining additional information concerning the contractor's determination, such as a specific provision of the policy, manual, law or regulation used in making the determination;

(iii) Information on the right to a redetermination if the beneficiary is dissatisfied with the outcome of the initial determination and instructions on how to request a redetermination; and

(iv) Any other requirements specified by CMS.

(b) *Notice of initial determination sent to providers and suppliers.* (1) An electronic or paper remittance advice (RA) notice is the notice of initial determination sent to providers and suppliers that accept assignment. The electronic RA must comply with the format and content requirements of the standard adopted for national use

by covered entities under the Health Insurance Portability and Accountability Act (HIPAA) and related CMS manual instructions. When a paper RA is mailed, it must comply with CMS manual instructions that parallel the HIPAA data content and coding requirements.

(2) The notice of initial determination must contain:

(i) The basis for any full or partial denial determination of services or items on the claim;

(ii) Information on the right to a redetermination if the provider or supplier is dissatisfied with the outcome of the initial determination;

(iii) All applicable claim adjustment reason and remark codes to explain the determination;

(iv) The source of the RA and who may be contacted if the provider or supplier requires further information;

(v) All content requirements of the standard adopted for national use by covered entities under HIPAA; and

(vi) Any other requirements specified by CMS.

§ 405.922 Time frame for processing initial determinations.

The contractor issues initial determinations on clean claims within 30 days of receipt if they are submitted by or on behalf of the beneficiary who received the items and/or services; otherwise, interest must be paid at the rate specified at 31 U.S.C. 3902(a) for the period beginning on the day after the required payment date and ending on the date payment is made.

§ 405.924 Actions that are initial determinations.

(a) *Applications and entitlement of individuals.* SSA makes initial determinations and processes reconsiderations with respect to an individual on the following:

(1) A determination with respect to entitlement to hospital insurance or supplementary medical insurance under Medicare.

(2) A disallowance of an individual's application for entitlement to hospital or supplementary medical insurance, if the individual fails to submit evidence requested by SSA to support the application. (SSA specifies in the initial determination the conditions of entitlement that the applicant failed to establish by not submitting the requested evidence).

(3) A denial of a request for withdrawal of an application for hospital or supplementary medical insurance, or a denial of a request for cancellation of a request for withdrawal.

(4) A determination as to whether an individual, previously determined as entitled to hospital or supplementary medical insurance, is no longer entitled to those benefits, including a determination based on nonpayment of premiums.

(b) *Claims made by or on behalf of beneficiaries.* The Medicare contractor makes initial determinations regarding claims for benefits under Medicare Part A and Part B. A finding that a request for payment or other submission does not meet the requirements for a Medicare claim as defined in § 424.32 of this chapter, is not considered an initial determination. An initial determination for purposes of this subpart includes, but is not limited to, determinations with respect to:

(1) If the items and/or services furnished are covered under title XVIII;

(2) In the case of determinations on the basis of section 1879(b) or (c) of the Act, if the beneficiary, or supplier who accepts assignment under § 424.55 of this chapter knew, or could reasonably have expected to know at the time the items or services were furnished, that the items or services were not covered;

(3) In the case of determinations on the basis of section 1842(l)(1) of the Act, if the beneficiary or physician knew, or could reasonably have expected to know at the time the services were furnished, that the services were not covered;

(4) Whether the deductible is met;

(5) The computation of the coinsurance amount;

(6) The number of days used for inpatient hospital, psychiatric hospital, or post-hospital extended care;

(7) The number of home health visits used;

(8) Periods of hospice care used;

(9) Requirements for certification and plan of treatment for physician services, durable medical equipment, therapies, inpatient hospitalization,

skilled nursing care, home health, hospice, and partial hospitalization services;

(10) The beginning and ending of a spell of illness, including a determination made under the presumptions established under §409.60(c)(2) of this chapter, and as specified in §409.60(c)(4) of this chapter;

(11) The medical necessity of services, or the reasonableness or appropriateness of placement of an individual at an acute level of patient care made by the Quality Improvement Organization (QIO) on behalf of the contractor in accordance with §476.86(c)(1) of this chapter;

(12) Any other issues having a present or potential effect on the amount of benefits to be paid under Part A or Part B of Medicare, including a determination as to whether there was an underpayment of benefits paid under Part A or Part B, and if so, the amount thereof;

(13) If a waiver of adjustment or recovery under sections 1870(b) and (c) of the Act is appropriate:

(i) When an overpayment of hospital insurance benefits or supplementary medical insurance benefits (including a payment under section 1814(e) of the Act) was made for an individual; or

(ii) For a Medicare Secondary Payer recovery claim against a beneficiary or against a provider or supplier.

(14) If a particular claim is not payable by Medicare based upon the application of the Medicare Secondary Payer provisions of section 1862(b) of the Act.

(15) Under the Medicare Secondary Payer provisions of sections 1862(b) of the Act that Medicare has a recovery claim against a provider, supplier, or beneficiary for services or items that were already paid by the Medicare program, except when the Medicare Secondary Payer recovery claim against the provider or supplier is based upon failure to file a proper claim as defined in part 411 of this chapter because this action is a reopening.

(c) *Determinations by QIOs.* An initial determination for purposes of this subpart also includes a determination made by a QIO that:

(1) A provider can terminate services provided to an individual when a physician certified that failure to continue the provision of those services is likely to place the individual's health at significant risk; or

(2) A provider can discharge an individual from the provider of services.

§405.926 Actions that are not initial determinations.

Actions that are not initial determinations and are not appealable under this subpart include, but are not limited to—

(a) Any determination for which CMS has sole responsibility, for example—

(1) If an entity meets the conditions for participation in the program;

(2) If an independent laboratory meets the conditions for coverage of services;

(b) The coinsurance amounts prescribed by regulation for outpatient services under the prospective payment system;

(c) Any issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS or a carrier has sole responsibility under Part B such as the establishment of a fee schedule set forth in part 414 of this chapter, or an inherent reasonableness adjustment pursuant to §405.502(g), and any issue regarding the cost report settlement process under Part A;

(d) Whether an individual's appeal meets the qualifications for expedited access to judicial review provided in §405.990;

(e) Any determination regarding whether a Medicare overpayment claim must be compromised, or collection action terminated or suspended under the Federal Claims Collection Act of 1966, as amended;

(f) Determinations regarding the transfer or discharge of residents of skilled nursing facilities in accordance with §483.12 of this chapter;

(g) Determinations regarding the readmission screening and annual resident review processes required by subparts C and E of part 483 of this chapter;

(h) Determinations for a waiver of Medicare Secondary Payer recovery under section 1862(b) of the Act;

(i) Determinations for a waiver of interest;

(j) Determinations for a finding regarding the general applicability of the Medicare Secondary Payer provisions (as opposed to the application of these provisions to a particular claim or claims for Medicare payment for benefits);

(k) Determinations under the Medicare Secondary Payer provisions of section 1862(b) of the Act that Medicare has a recovery against an entity that was or is required or responsible (directly, as an insurer or self-insurer, as a third party administrator, as an employer that sponsors or contributes to a group health plan or a large group health plan, or otherwise,) to make payment for services or items that were already reimbursed by the Medicare program;

(l) A contractor's, QIC's, ALJ's, or MAC's determination or decision to reopen or not to reopen an initial determination, redetermination, reconsideration, hearing decision, or review decision;

(m) Determinations that CMS or its contractors may participate in or act as parties in an ALJ hearing or MAC review;

(n) Determinations that a provider or supplier failed to submit a claim timely or failed to submit a timely claim despite being requested to do so by the beneficiary or the beneficiary's subrogee;

(o) Determinations with respect to whether an entity qualifies for an exception to the electronic claims submission requirement under part 424 of this chapter;

(p) Determinations by the Secretary of sustained or high levels of payment errors in accordance with section 1893(f)(3)(A) of the Act;

(q) A contractor's prior determination related to coverage of physicians' services;

(r) Requests for anticipated payment under the home health prospective payment system under §409.43(c)(ii)(2) of this chapter; and

(s) Claim submissions on forms or formats that are incomplete, invalid, or do not meet the requirements for a Medicare claim and returned or rejected to the provider or supplier.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005]

§405.927 Initial determinations subject to the reopenings process.

Minor errors or omissions in an initial determination must be corrected only through the contractor's reopenings process under §405.980(a)(3).

§405.928 Effect of the initial determination.

(a) An initial determination described in §405.924(a) is binding unless it is revised or reconsidered in accordance with 20 CFR 404.907, or revised as a result of a reopening in accordance with 20 CFR 404.988.

(b) An initial determination described in §405.924(b) is binding upon all parties to the initial determination unless—

(1) A redetermination is completed in accordance with §405.940 through §405.958; or

(2) The initial determination is revised as a result of a reopening in accordance with §405.980.

(c) An initial determination listed in §405.924(b) where a party submits a timely, valid request for redetermination under §405.942 through §405.944 must be processed as a redetermination under §405.948 through §405.958 unless the initial determination involves a clerical error or other minor error or omission.

REDETERMINATIONS

§405.940 Right to a redetermination.

A person or entity that may be a party to a redetermination in accordance with §405.906(b) and that is dissatisfied with an initial determination may request a redetermination by a contractor in accordance with §405.940 through §405.958, regardless of the amount in controversy.

§405.942 Time frame for filing a request for a redetermination.

(a) *Time frame for filing a request.* Except as provided in paragraph (b) of this section, any request for redetermination must be filed within 120 calendar days from the date a party receives the notice of the initial determination.

(1) For purposes of this section, the date of receipt of the initial determination will be presumed to be 5 days after

the date of the notice of initial determination, unless there is evidence to the contrary.

(2) The request is considered as filed on the date it is received by the contractor.

(b) *Extending the time frame for filing a request. General rule.* If the 120-day period in which to file a request for a redetermination has expired and a party shows good cause, the contractor may extend the time frame for filing a request for redetermination.

(1) *How to request an extension.* A party may file a request for an extension of time for filing a request for a redetermination with the contractor. The party should include any evidence supporting the request for extension. The request for redetermination extension must—

(i) Be in writing;

(ii) State why the request for redetermination was not filed within the required time frame; and

(iii) Meet the requirements of § 405.944.

(2) *How the contractor determines if good cause exists.* In determining if a party has good cause for missing a deadline to request a redetermination, the contractor considers—

(i) The circumstances that kept the party from making the request on time;

(ii) If the contractor's action(s) misled the party; and

(iii) If the party had or has any physical, mental, educational, or linguistic limitations, including any lack of facility with the English language, that prevented the party from filing a timely request or from understanding or knowing about the need to file a timely request.

(3) *Examples of good cause.* Examples of circumstances when good cause may be found to exist include, but are not limited to, the following situations:

(i) The party was prevented by serious illness from contacting the contractor in person, in writing, or through a friend, relative, or other person; or

(ii) The party had a death or serious illness in his or her immediate family; or

(iii) Important records of the party were destroyed or damaged by fire or other accidental cause; or

(iv) The contractor gave the party incorrect or incomplete information about when and how to request a redetermination; or

(v) The party did not receive notice of the determination or decision; or

(vi) The party sent the request to a Government agency in good faith within the time limit, and the request did not reach the appropriate contractor until after the time period to file a request expired.

§ 405.944 Place and method of filing a request for a redetermination.

(a) *Filing location.* The request for redetermination must be filed with the contractor indicated on the notice of initial determination.

(b) *Content of redetermination request.* The request for redetermination must be in writing and should be made on a standard CMS form. A written request that is not made on a standard CMS form is accepted if it contains the same required elements as follows:

(1) The beneficiary's name;

(2) The Medicare health insurance claim number;

(3) Specific service(s) and/or item(s) for which the redetermination is being requested and the specific date(s) of the service;

(4) The name and signature of the party or the representative of the party.

(c) *Requests for redetermination by more than one party.* If more than one party timely files a request for redetermination on the same claim before a redetermination is made on the first timely filed request, the contractor must consolidate the separate requests into one proceeding and issue one redetermination.

§ 405.946 Evidence to be submitted with the redetermination request.

(a) *Evidence submitted with the request.* When filing the request for redetermination, a party must explain why it disagrees with the contractor's determination and should include any evidence that the party believes should be considered by the contractor in making its redetermination.

(b) *Evidence submitted after the request.* When a party submits additional evidence after filing the request for redetermination, the contractor's 60-day decision-making time frame is automatically extended for up to 14 calendar days for each submission.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005]

§ 405.948 Conduct of a redetermination.

A redetermination consists of an independent review of an initial determination. In conducting a redetermination, the contractor reviews the evidence and findings upon which the initial determination was based, and any additional evidence the parties submit or the contractor obtains on its own. An individual who was not involved in making the initial determination must make a redetermination. The contractor may raise and develop new issues that are relevant to the claims in the particular case.

§ 405.950 Time frame for making a redetermination.

(a) *General rule.* The contractor mails, or otherwise transmits, written notice of the redetermination or dismissal to the parties to the redetermination at their last known addresses within 60 calendar days of the date the contractor receives a timely filed request for redetermination.

(b) *Exceptions.* (1) If a contractor grants an appellant's request for an extension of the 120-day filing deadline made in accordance with § 405.942(b), the 60-day decision-making time frame begins on the date the contractor receives the late-filed request for redetermination, or when the request for an extension is granted, whichever is later.

(2) If a contractor receives from multiple parties timely requests for redetermination of a claim determination, consistent with § 405.944(c), the contractor must issue a redetermination or dismissal within 60 days of the latest filed request.

(3) If a party submits additional evidence after the request for redetermination is filed, the contractor's 60-day decision-making time frame is extended for up to 14 calendar days for each submission, consistent with § 405.946(b).

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005]

§ 405.952 Withdrawal or dismissal of a request for a redetermination.

(a) *Withdrawing a request.* A party that files a request for redetermination may withdraw its request by filing a written and signed request for withdrawal. The request for withdrawal must contain a clear statement that the appellant is withdrawing the request for a redetermination and does not intend to proceed further with the appeal. The request must be received in the contractor's mailroom before a redetermination is issued. The appeal will proceed with respect to any other parties that have filed a timely request for redetermination.

(b) *Dismissing a request.* A contractor dismisses a redetermination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting a redetermination is not a proper party under § 405.906(b) or does not otherwise have a right to a redetermination under section 1869(a) of the Act;

(2) When the contractor determines the party failed to make out a valid request for redetermination that substantially complies with § 405.944;

(3) When the party fails to file the redetermination request within the proper filing time frame in accordance with § 405.942;

(4) When a beneficiary or the beneficiary's representative files a request for redetermination, but the beneficiary dies while the request is pending, and all of the following criteria apply:

(i) The beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the contractor considers if the surviving spouse or estate remains liable for the services for which payment was denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation of liability provisions based on the denial of payment for services at issue;

(ii) No other individual or entity with a financial interest in the case wishes to pursue the appeal; and

(iii) No other party filed a valid and timely redetermination request under §405.942 and §405.944;

(5) When a party filing the redetermination request submits a timely written request for withdrawal with the contractor; or

(6) When the contractor has not issued an initial determination on the claim or the matter for which a redetermination is sought.

(c) *Notice of dismissal.* A contractor mails or otherwise transmits a written notice of the dismissal of the redetermination request to the parties at their last known addresses. The notice states that there is a right to request that the contractor vacate the dismissal action.

(d) *Vacating a dismissal.* If good and sufficient cause is established, a contractor may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(e) *Effect of dismissal.* The dismissal of a request for redetermination is final and binding, unless it is modified or reversed by a QIC under §405.974(b) or vacated under paragraph (d) of this section.

§405.954 Redetermination.

Upon the basis of the evidence of record, the contractor adjudicates the claim(s), and renders a redetermination affirming or reversing, in whole or in part, the initial determination in question.

§405.956 Notice of a redetermination.

(a) *Notification to parties*—(1) *General rule.* Written notice of a redetermination affirming, in whole or in part, the initial determination must be mailed or otherwise transmitted to all parties at their last known addresses in accordance with the time frames established in §405.950. Written notice of a redetermination fully reversing the initial determination must be mailed or otherwise transmitted to the appellant in accordance with the time frames established in §405.950. If the redetermination results in issuance of supplemental payment to a provider or supplier, the Medicare contractor must also issue an electronic or paper RA notice to the provider or supplier.

(2) *Overpayment cases involving multiple beneficiaries who have no liability.* In an overpayment case involving multiple beneficiaries who have no liability, the contractor may issue a written notice only to the appellant.

(b) *Content of the notice for affirmations, in whole or in part.* For decisions that are affirmations, in whole or in part, of the initial determination, the redetermination must be written in a manner calculated to be understood by a beneficiary, and contain—

(1) A clear statement indicating the extent to which the redetermination is favorable or unfavorable;

(2) A summary of the facts, including, as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

(3) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case;

(4) A summary of the rationale for the redetermination in clear, understandable language;

(5) Notification to the parties of their right to a reconsideration and a description of the procedures that a party must follow in order to request a reconsideration, including the time frame within which a reconsideration must be requested;

(6) A statement of any specific missing documentation that must be submitted with a request for a reconsideration, if applicable;

(7) A statement that all evidence the appellant wishes to introduce during the claim appeals process should be submitted with the request for a reconsideration;

(8) Notification that evidence not submitted to the QIC as indicated in paragraph (b)(6) of this section, is not considered at an ALJ hearing or further appeal, unless the appellant demonstrates good cause as to why that evidence was not provided previously; and

(9) The procedures for obtaining additional information concerning the redetermination, such as specific provisions of the policy, manual, or regulation used in making the redetermination.

(10) Any other requirements specified by CMS.

(c) *Content of the notice for a full reversal.* For decisions that are full reversals of the initial determination, the redetermination must be in writing and contain—

(1) A clear statement indicating that the redetermination is wholly favorable;

(2) Any other requirements specified by CMS.

(d) *Exception for beneficiary appeal requests.* (1) The notice must inform beneficiary appellants that the requirements of paragraph (b)(8) of this section are not applicable for purposes of beneficiary appeals.

(2) This exception does not apply for appeal requests from beneficiaries who are represented by providers or suppliers.

§ 405.958 Effect of a redetermination.

In accordance with section 1869 (a)(3)(D) of the Act, once a redetermination is issued, it becomes part of the initial determination. The redetermination is final and binding upon all parties unless—

(a) A reconsideration is completed in accordance with § 405.960 through § 405.978; or

(b) The redetermination is revised as a result of a reopening in accordance with § 405.980.

RECONSIDERATION

§ 405.960 Right to a reconsideration.

A person or entity that is a party to a redetermination made by a contractor as described under § 405.940 through § 405.958, and is dissatisfied with that determination, may request a reconsideration by a QIC in accordance with § 405.962 through § 405.966, regardless of the amount in controversy.

§ 405.962 Timeframe for filing a request for a reconsideration.

(a) *Timeframe for filing a request.* Except as provided in paragraph (b) of this section, any request for a reconsideration must be filed within 180 calendar days from the date the party receives the notice of the redetermination.

(1) For purposes of this section, the date of receipt of the redetermination will be presumed to be 5 days after the date of the notice of redetermination, unless there is evidence to the contrary.

(2) For purposes of meeting the 180-day filing deadline, the request is considered as filed on the date it is received by the QIC.

(b) *Extending the time for filing a request*—(1) *General rule.* A QIC may extend the 180-day timeframe for filing a request for reconsideration for good cause.

(2) *How to request an extension.* A party to the redetermination must file its request for an extension of the time for filing the reconsideration request with its request for reconsideration. A party should include evidence to support the request for extension. The request for reconsideration and request for extension must—

(i) Be in writing;

(ii) State why the request for reconsideration was not filed within the required timeframe; and

(iii) Meet the requirements of § 405.964.

(3) *How the QIC determines whether good cause exists.* In determining whether a party has good cause for missing a deadline to request reconsideration, the QIC applies the good cause provisions contained in § 405.942(b)(2) and (b)(3).

§ 405.964 Place and method of filing a request for a reconsideration.

(a) *Filing location.* The request for reconsideration must be filed with the QIC indicated on the notice of redetermination.

(b) *Content of reconsideration request.* The request for reconsideration must be in writing and should be made on a standard CMS form. A written request that is not made on a standard CMS form is accepted if it contains the same required elements, as follows:

(1) The beneficiary's name;

(2) Medicare health insurance claim number;

(3) Specific service(s) and item(s) for which the reconsideration is requested and the specific date(s) of service;

(4) The name and signature of the party or the representative of the party; and

(5) The name of the contractor that made the redetermination.

(c) *Requests for reconsideration by more than one party.* If more than one party timely files a request for reconsideration on the same claim before a reconsideration is made on the first timely filed request, the QIC must consolidate the separate requests into one proceeding and issue one reconsideration.

§ 405.966 Evidence to be submitted with the reconsideration request.

(a) *Evidence submitted with the request.* When filing a request for reconsideration, a party should present evidence and allegations of fact or law related to the issue in dispute and explain why it disagrees with the initial determination, including the redetermination.

(1) This evidence must include any missing documentation identified in the notice of redetermination, consistent with § 405.956(b)(6).

(2) Absent good cause, failure to submit all evidence, including documentation requested in the notice of redetermination prior to the issuance of the notice of reconsideration precludes subsequent consideration of that evidence.

(b) *Evidence submitted after the request.* Each time a party submits additional evidence after filing the request for reconsideration, the QIC's 60-day decisionmaking timeframe is automatically extended by up to 14 calendar days for each submission. This extension does not apply to timely submissions of documentation specifically requested by a QIC, unless the documentation was originally requested in the notice of redetermination.

(c) *Exception for beneficiaries and State Medicaid Agencies that file reconsideration requests.* (1) Beneficiaries and State Medicaid Agencies that file requests for reconsideration are not required to comply with the requirements of paragraph (a) of this section. However, the automatic 14-day extension described in paragraph (b) of this section applies to each evidence submission made after the request for reconsideration is filed.

(2) Beneficiaries who are represented by providers or suppliers must comply with the requirements of paragraph (a) of this section.

§ 405.968 Conduct of a reconsideration.

(a) *General rules.* (1) A reconsideration consists of an independent, on-the-record review of an initial determination, including the redetermination and all issues related to payment of the claim. In conducting a reconsideration, the QIC reviews the evidence and findings upon which the initial determination, including the redetermination, was based, and any additional evidence the parties submit or that the QIC obtains on its own. If the initial determination involves a finding on whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A) of the Act), a QIC's reconsideration must involve consideration by a panel of physicians or other appropriate health care professionals, and be based on clinical experience, the patient's medical records, and medical, technical, and scientific evidence of record to the extent applicable.

(b) *Authority of the QIC.* (1) National coverage determinations (NCDs), CMS Rulings, and applicable laws and regulations are binding on the QIC.

(2) QICs are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but give substantial deference to these policies if they are applicable to a particular case. A QIC may decline to follow a policy, if the QIC determines, either at a party's request or at its own discretion, that the policy does not apply to the facts of the particular case.

(3) If a QIC declines to follow a policy in a particular case, the QIC's reconsideration explains the reasons why the policy was not followed.

(4) A QIC's decision to decline to follow a policy under this section applies only to the specific claim being reconsidered and does not have precedential effect.

(5) A QIC may raise and develop new issues that are relevant to the claims

in a particular case provided that the contractor rendered a redetermination with respect to the claims.

(c) *Qualifications of the QIC's panel members.* (1) Members of a QIC's panel who conduct reconsiderations must have sufficient medical, legal, and other expertise, including knowledge of the Medicare program.

(2) When a redetermination is made with respect to whether an item or service is reasonable and necessary (section 1862(a)(1)(A) of the Act), the QIC designates a panel of physicians or other appropriate health care professionals to consider the facts and circumstances of the redetermination.

(3) Where a claim pertains to the furnishing of treatment by a physician, or the provision of items or services by a physician, a reviewing professional must be a physician.

(d) *Disqualification of a QIC panel member.* No physician or health care professional employed by or otherwise working for a QIC may review determinations regarding—

(1) Health care services furnished to a patient if that physician or health care professional was directly responsible for furnishing those services; or

(2) Health care services provided in or by an institution, organization, or agency, if that physician or health care professional or any member of the physician's family or health care professional's family has, directly or indirectly, a significant financial interest in that institution, organization, or agency (see the term family member as defined in § 405.902).

§ 405.970 Timeframe for making a reconsideration.

(a) *General rule.* Within 60 calendar days of the date the QIC receives a timely filed request for reconsideration or any additional time provided by paragraph (b) of this section, the QIC mails, or otherwise transmits to the parties at their last known addresses, written notice of—

(1) The reconsideration;

(2) Its inability to complete its review within 60 days in accordance with paragraphs (c) through (e) of this section; or

(3) Dismissal.

(b) *Exceptions.* (1) If a QIC grants an appellant's request for an extension of the 180-day filing deadline made in accordance with § 405.962(b), the QIC's 60-day decision-making timeframe begins on the date the QIC receives the late filed request for reconsideration, or when the request for an extension that meets the requirements of § 405.962(b) is granted, whichever is later.

(2) If a QIC receives timely requests for reconsideration from multiple parties, consistent with § 405.964(c), the QIC must issue a reconsideration, notice that it cannot complete its review, or dismissal within 60 days for each submission of the latest filed request.

(3) Each time a party submits additional evidence after the request for reconsideration is filed, the QIC's 60-day decisionmaking timeframe is extended by up to 14 days for each submission, consistent with § 405.966(b).

(c) *Responsibilities of the QIC.* Within 60 days of receiving a request for a reconsideration, or any additional time provided for under paragraph (b) of this section, a QIC must take one of the following actions:

(1) Notify all parties of its reconsideration, consistent with § 405.976.

(2) Notify the parties that it cannot complete the reconsideration by the deadline specified in paragraph (b) of this section and offer the appellant the opportunity to escalate the appeal to an ALJ. The QIC continues to process the reconsideration unless it receives a written request from the appellant to escalate the case to an ALJ after the adjudication period has expired.

(d) *Responsibilities of the appellant.* If an appellant wishes to exercise the option of escalating the case to an ALJ, the appellant must notify the QIC in writing.

(e) *Actions following appellant's notice.* (1) If the appellant fails to notify the QIC, or notifies the QIC that the appellant does not choose to escalate the case, the QIC completes its reconsideration and notifies the appellant of its action consistent with § 405.972 or § 405.976.

(2) If the appellant notifies the QIC that the appellant wishes to escalate the case, the QIC must take one of the following actions within 5 days of receipt of the notice or 5 days from the

end of the applicable adjudication period under paragraph (a) or (b) of this section:

(i) Complete its reconsideration and notify all parties of its decision consistent with §405.972 or §405.976.

(ii) Acknowledge the escalation notice in writing and forward the case file to the ALJ hearing office.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005]

§405.972 Withdrawal or dismissal of a request for a reconsideration.

(a) *Withdrawing a request.* An appellant that files a request for reconsideration may withdraw its request by filing a written and signed request for withdrawal. The request for withdrawal must—

(1) Contain a clear statement that the appellant is withdrawing the request for reconsideration and does not intend to proceed further with the appeal.

(2) Be received in the QIC's mailroom before the reconsideration is issued.

(b) *Dismissing a request.* A QIC dismisses a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting reconsideration is not a proper party under §405.906(b) or does not otherwise have a right to a reconsideration under section 1869(b) of the Act;

(2) When the QIC determines that the party failed to make out a valid request for reconsideration that substantially complies with §405.964(a) and (b);

(3) When the party fails to file the reconsideration request in accordance with the timeframes established in §405.962;

(4) When a beneficiary or the beneficiary's representative files a request for reconsideration, but the beneficiary dies while the request is pending, and all of the following criteria apply:

(i) The beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the QIC considers if the surviving spouse or estate remains liable for the services for which payment was denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation of liability provisions based on the denial of payment for services at issue;

(ii) No other individual or entity with a financial interest in the case wishes to pursue the appeal; and

(iii) No other party to the redetermination filed a valid and timely request for reconsideration under §405.962 and §405.964.

(5) When a party filing for the reconsideration submits a written request of withdrawal to the QIC and satisfies the criteria set forth in paragraph (a) of this section before the reconsideration has been issued; or

(6) When the contractor has not issued a redetermination on the initial determination for which a reconsideration is sought.

(c) *Notice of dismissal.* A QIC mails or otherwise transmits written notice of the dismissal of the reconsideration request to the parties at their last known addresses. The notice states that there is a right to request that the contractor vacate the dismissal action. The appeal will proceed with respect to any other parties that have filed a timely request for reconsideration.

(d) *Vacating a dismissal.* If good and sufficient cause is established, a QIC may vacate its dismissal of a request for reconsideration within 6 months of the date of the notice of dismissal.

(e) *Effect of dismissal.* The dismissal of a request for reconsideration is final and binding, unless it is modified or reversed by an ALJ under §405.1004 or vacated under paragraph (d) of this section.

§405.974 Reconsideration.

(a) *Reconsideration of a contractor determination.* Except as provided in §405.972, upon the basis of the evidence of record, the QIC must issue a reconsideration affirming or reversing, in whole or in part, the initial determination, including the redetermination, in question.

(b) *Reconsideration of contractor's dismissal of a redetermination request.* (1) A party to a contractor's dismissal of a request for redetermination has a right to have the dismissal reviewed by a QIC, if the party files a written request for review of the dismissal with the QIC within 60 days after receipt of the contractor's notice of dismissal.

(i) For purposes of this section, the date of receipt of the contractor's notice of dismissal is presumed to be 5 days after the date of the notice of dismissal, unless there is evidence to the contrary.

(ii) For purposes of meeting the 60-day filing deadline, the request is considered as filed on the date it is received by the QIC indicated on the notice of dismissal.

(2) If the QIC determines that the contractor's dismissal was in error, it vacates the dismissal and remands the case to the contractor for a redetermination.

(3) A QIC's reconsideration of a contractor's dismissal of a redetermination request is final and not subject to any further review.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005]

§ 405.976 Notice of a reconsideration.

(a) *Notification to parties*—(1) *General rules.* (i) Written notice of the reconsideration must be mailed or otherwise transmitted to all parties at their last known addresses, in accordance with the timeframes established in § 405.970(a) or (b).

(ii) The notice must be written in a manner reasonably calculated to be understood by a beneficiary.

(iii) The QIC must promptly notify the entity responsible for payment of claims under Part A or Part B of its reconsideration. If the reconsideration results in issuance of supplemental payment to a provider or supplier, the Medicare contractor must also issue an electronic or paper RA notice to the provider or supplier.

(2) *Overpayment cases involving multiple beneficiaries who have no liability.* In an overpayment case involving multiple beneficiaries who have no liability, the QIC may issue a written notice only to the appellant.

(b) *Content of the notice.* The reconsideration must be in writing and contain—

(1) A clear statement indicating whether the reconsideration is favorable or unfavorable;

(2) A summary of the facts, including as appropriate, a summary of the clinical or scientific evidence used in making the reconsideration;

(3) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies, apply to the facts of the case, including, where applicable, the rationale for declining to follow an LCD, LMRP, or CMS program guidance;

(4) In the case of a determination on whether an item or service is reasonable or necessary under section 1862(a)(1)(A) of the Act, an explanation of the medical and scientific rationale for the decision;

(5) A summary of the rationale for the reconsideration.

(i) If the notice of redetermination indicated that specific documentation should be submitted with the reconsideration request, and the documentation was not submitted with the request for reconsideration, the summary must indicate how the missing documentation affected the reconsideration; and

(ii) The summary must also specify that, consistent with § 405.956(b)(8) and § 405.966(b), all evidence, including evidence requested in the notice of redetermination, that is not submitted prior to the issuance of the reconsideration will not be considered at an ALJ level, or made part of the administrative record, unless the appellant demonstrates good cause as to why the evidence was not provided prior to the issuance of the QIC's reconsideration. This requirement does not apply to beneficiaries, unless the beneficiary is represented by a provider or supplier or to State Medicaid Agencies;

(6) Information concerning to the parties' right to an ALJ hearing, including the applicable amount in controversy requirement and aggregation provisions;

(7) A statement of whether the amount in controversy needed for an ALJ hearing is met when the reconsideration is partially or fully unfavorable;

(8) A description of the procedures that a party must follow in order to obtain an ALJ hearing of an expedited reconsideration, including the time frame under which a request for an ALJ hearing must be filed;

(9) If appropriate, advice as to the requirements for use of the expedited access to judicial review process set forth in §405.990;

(10) The procedures for obtaining additional information concerning the reconsideration, such as specific provisions of the policy, manual, or regulation used in making the reconsideration; and

(11) Any other requirements specified by CMS.

§405.978 Effect of a reconsideration.

A reconsideration is final and binding on all parties, unless—

(a) An ALJ decision is issued in accordance to a request for an ALJ hearing made in accordance with §405.1014;

(b) A review entity issues a decision in accordance to a request for expedited access to judicial review under §405.990; or

(c) The reconsideration is revised as a result of a reopening in accordance with §405.980.

REOPENINGS

§405.980 Reopenings of initial determinations, redeterminations, and reconsiderations, hearings and reviews.

(a) *General rules.* (1) A reopening is a remedial action taken to change a final determination or decision that resulted in either an overpayment or underpayment, even though the final determination or decision may have been correct at the time it was made based on the evidence of record. That action may be taken by—

(i) A contractor to revise the initial determination or redetermination;

(ii) A QIC to revise the reconsideration;

(iii) An ALJ to revise the hearing decision; or

(iv) The MAC to revise the hearing or review decision.

(2) If a contractor issues a denial of a claim because it did not receive requested documentation during medical review and the party subsequently requests a redetermination, the contractor must process the request as a reopening.

(3) Notwithstanding paragraph (a)(4) of this section, a contractor must process clerical errors (which includes minor errors and omissions) as reopenings, instead of as redeterminations as specified in §405.940. If the contractor receives a request for reopening and disagrees that the issue is a clerical error, the contractor must dismiss the reopening request and advise the party of any appeal rights, provided the timeframe to request an appeal on the original denial has not expired. For purposes of this section, clerical error includes human or mechanical errors on the part of the party or the contractor such as—

(i) Mathematical or computational mistakes;

(ii) Inaccurate data entry; or

(iii) Denials of claims as duplicates.

(4) When a party has filed a valid request for an appeal of an initial determination, redetermination, reconsideration, hearing, or MAC review, no adjudicator has jurisdiction to reopen an issue on a claim that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the contractor, QIC, ALJ, or MAC may reopen as set forth in this section.

(5) The contractor's, QIC's, ALJ's, or MAC's decision on whether to reopen is final and not subject to appeal.

(6) A determination under the Medicare secondary payer provisions of section 1862(b) of the Act that Medicare has an MSP recovery claim for services or items that were already reimbursed by the Medicare program is not a reopening, except where the recovery claim is based upon a provider's or supplier's failure to demonstrate that it filed a proper claim as defined in part 411 of this chapter.

(b) *Time frames and requirements for reopening initial determinations and redeterminations initiated by a contractor.* A contractor may reopen and revise its initial determination or redetermination on its own motion—

(1) Within 1 year from the date of the initial determination or redetermination for any reason.

(2) Within 4 years from the date of the initial determination or redetermination for good cause as defined in §405.986.

(3) At any time if there exists reliable evidence as defined in §405.902 that the initial determination was procured

by fraud or similar fault as defined in § 405.902.

(4) At anytime if the initial determination is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error on which that determination was based.

(5) At any time to effectuate a decision issued under the coverage appeals process.

(c) *Time frame and requirements for reopening initial determinations and redeterminations requested by a party.* (1) A party may request that a contractor reopen its initial determination or redetermination within 1 year from the date of the initial determination or redetermination for any reason.

(2) A party may request that a contractor reopen its initial determination or redetermination within 4 years from the date of the initial determination or redetermination for good cause in accordance with § 405.986.

(3) A party may request that a contractor reopen its initial determination at any time if the initial determination is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error on which that determination was based. Third party payer error does not constitute clerical error. *See* § 405.986(c).

(d) *Time frame and requirements for reopening reconsiderations, hearing decisions and reviews initiated by a QIC, ALJ, or the MAC.* (1) A QIC may reopen its reconsideration on its own motion within 180 days from the date of the reconsideration for good cause in accordance with § 405.986. If the QIC's reconsideration was procured by fraud or similar fault, then the QIC may reopen at any time.

(2) An ALJ or the MAC may reopen a hearing decision on its own motion within 180 days from the date of the decision for good cause in accordance with § 405.986. If the hearing decision was procured by fraud or similar fault, then the ALJ or the MAC may reopen at any time.

(3) The MAC may reopen its review decision on its own motion within 180 days from the date of the review decision for good cause in accordance with § 405.986. If the MAC's decision was procured by fraud or similar fault, then the MAC may reopen at any time.

(e) *Time frames and requirements for reopening reconsiderations, hearing decisions, and reviews requested by a party.* (1) A party to a reconsideration may request that a QIC reopen its reconsideration within 180 days from the date of the reconsideration for good cause in accordance with § 405.986.

(2) A party to a hearing may request that an ALJ or the MAC reopen a hearing decision within 180 days from the date of the hearing decision for good cause in accordance with § 405.986.

(3) A party to a review may request that the MAC reopen its decision within 180 days from the date of the review decision for good cause in accordance with § 405.986.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005]

§ 405.982 Notice of a revised determination or decision.

(a) *When adjudicators initiate reopenings.* When any determination or decision is reopened and revised as provided in § 405.980, the contractor, QIC, ALJ, or the MAC must mail its revised determination or decision to the parties to that determination or decision at their last known address. In the case of a full or partial reversal resulting in issuance of a payment to a provider or supplier, a revised electronic or paper remittance advice notice must be issued by the Medicare contractor. An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

(b) *Reopenings initiated at the request of a party.* The contractor, QIC, ALJ, or the MAC must mail its revised determination or decision to the parties to that determination or decision at their last known address. In the case of a full or partial reversal resulting in issuance of a payment to a provider or supplier, a revised electronic or paper remittance advice notice must be issued by the Medicare contractor. An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

§ 405.984 Effect of a revised determination or decision.

(a) *Initial determinations.* The revision of an initial determination is binding upon all parties unless a party files a written request for a redetermination that is accepted and processed in accordance with § 405.940 through § 405.958.

(b) *Redeterminations.* The revision of a redetermination is binding upon all parties unless a party files a written request for a QIC reconsideration that is accepted and processed in accordance with § 405.960 through § 405.978.

(c) *Reconsiderations.* The revision of a reconsideration is binding upon all parties unless a party files a written request for an ALJ hearing that is accepted and processed in accordance with § 405.1000 through § 405.1064.

(d) *ALJ Hearing decisions.* The revision of a hearing decision is binding upon all parties unless a party files a written request for a MAC review that is accepted and processed in accordance with § 405.1100 through § 405.1130.

(e) *MAC review.* The revision of a MAC review is binding upon all parties unless a party files a civil action in which a Federal district court accepts jurisdiction and issues a decision.

(f) *Appeal of only the portion of the determination or decision revised by the reopening.* Only the portion of the initial determination, redetermination, reconsideration, or hearing decision revised by the reopening may be subsequently appealed.

(g) *Effect of a revised determination or decision.* A revised determination or decision is binding unless it is appealed or otherwise reopened.

§ 405.986 Good cause for reopening.

(a) *Establishing good cause.* Good cause may be established when—

(1) There is new and material evidence that—

(i) Was not available or known at the time of the determination or decision; and

(ii) May result in a different conclusion; or

(2) The evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision.

(b) *Change in substantive law or interpretative policy.* A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, or a change in legal interpretation or policy by SSA in a regulation, SSA ruling, or SSA general instruction in entitlement appeals, whether made in response to judicial precedent or otherwise, is not a basis for reopening a determination or hearing decision under this section. This provision does not preclude contractors from conducting reopenings to effectuate coverage decisions issued under the authority granted by section 1869(f) of the Act.

(c) *Third party payer error.* A request to reopen a claim based upon a third party payer's error in making a primary payment determination when Medicare processed the claim in accordance with the information in its system of records or on the claim form does not constitute good cause for reopening.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005]

Expedited Access to Judicial Review

§ 405.990 Expedited access to judicial review.

(a) *Process for expedited access to judicial review.* (1) For purposes of this section, a ''review entity'' means an entity of up to three reviewers who are ALJs or members of the Departmental Appeals Board (DAB), as determined by the Secretary.

(2) In order to obtain expedited access to judicial review (EAJR), a review entity must certify that the Medicare Appeals Council (MAC) does not have the authority to decide the question of law or regulation relevant to the matters in dispute and that there is no material issue of fact in dispute.

(3) A party may make a request for EAJR only once with respect to a question of law or regulation for a specific matter in dispute in an appeal.

(b) *Conditions for making the expedited appeals request.* (1) A party may request EAJR in place of an ALJ hearing or MAC review if the following conditions are met:

(i) A QIC has made a reconsideration determination and the party has filed a request for—

(A) An ALJ hearing in accordance with §405.1002 and a final decision of the ALJ has not been issued;

(B) MAC review in accordance with §405.1102 and a final decision of the MAC has not been issued; or

(ii) The appeal has been escalated from the QIC to the ALJ level after the period described in §405.970(a) and §405.970(b) has expired, and the QIC does not issue a final action within the time frame described in §405.970(e).

(2) The requestor is a party, as defined in paragraph (e) of this section.

(3) The amount remaining in controversy meets the requirements of §405.1006(b) or (c).

(4) If there is more than one party to the reconsideration, hearing, or MAC review, each party concurs, in writing, with the request for the EAJR.

(5) There are no material issues of fact in dispute.

(c) *Content of the request for EAJR.* The request for EAJR must—

(1) Allege that there are no material issues of fact in dispute and identify the facts that the requestor considers material and that are not disputed; and

(2) Assert that the only factor precluding a decision favorable to the requestor is—

(i) A statutory provision that is unconstitutional, or a provision of a regulation or national coverage determination and specify the statutory provision that the requestor considers unconstitutional or the provision of a regulation or a national coverage determination that the requestor considers invalid, or

(ii) A CMS Ruling that the requester considers invalid;

(3) Include a copy of any QIC reconsideration and of any ALJ hearing decision that the requester has received;

(4) If any QIC reconsideration or ALJ hearing decision was based on facts that the requestor is disputing, state why the requestor considers those facts to be immaterial; and

(5) If any QIC reconsideration or ALJ hearing decision was based on a provision of a law, regulation, national coverage determination or CMS Ruling in addition to the one the requestor considers unconstitutional or invalid, a statement as to why further administrative review of how that provision applies to the facts is not necessary.

(d) *Place and time for an EAJR request*—(1) *Method and place for filing request.* The requestor may include an EAJR request in his or her request for an ALJ hearing or MAC review, or, if an appeal is already pending with an ALJ or the MAC, file a written EAJR request with the ALJ hearing office or MAC where the appeal is being considered. The ALJ hearing office or MAC forwards the request to the review entity within 5 calendar days of receipt.

(2) *Time of filing request.* The party may file a request for the EAJR—

(i) If the party has requested a hearing, at any time before receipt of the notice of the ALJ's decision; or

(ii) If the party has requested MAC review, at any time before receipt of notice of the MAC's decision.

(e) *Parties to the EAJR.* The parties to the EAJR are the persons or entities who were parties to the QIC's reconsideration determination and, if applicable, to the ALJ hearing.

(f) *Determination on EAJR request.* (1) The review entity described in paragraph (a) of this section will determine whether the request for EAJR meets all of the requirements of paragraphs (b), (c), and (d) of this section.

(2) Within 60 days after the date the review entity receives a request and accompanying documents and materials meeting the conditions in paragraphs (b), (c), and (d) of this section, the review entity will issue either a certification in accordance to paragraph (g) of this section or a denial of the request.

(3) A determination by the review entity either certifying that the requirements for EAJR are met pursuant to paragraph (g) of this section or denying the request is final and not subject to review by the Secretary.

(4) If the review entity fails to make a determination within the time frame specified in paragraph (f)(2) of this section, then the requestor may bring a civil action in Federal district court within 60 days of the end of the time frame.

(g) *Certification by the review entity.* If a party meets the requirements for the

EAJR, the review entity certifies in writing that—

(1) The material facts involved in the claim are not in dispute;

(2) Except as indicated in paragraph (g)(3) of this section, the Secretary's interpretation of the law is not in dispute;

(3) The sole issue(s) in dispute is the constitutionality of a statutory provision, or the validity of a provision of a regulation, CMS Ruling, or national coverage determination;

(4) But for the provision challenged, the requestor would receive a favorable decision on the ultimate issue (such as whether a claim should be paid); and

(5) The certification by the review entity is the Secretary's final action for purposes of seeking expedited judicial review.

(h) *Effect of certification by the review entity.* If an EAJR request results in a certification described in paragraph (g) of this section—

(1) The party that requested the EAJR is considered to have waived any right to completion of the remaining steps of the administrative appeals process regarding the matter certified.

(2) The requestor has 60 days, beginning on the date of the review entity's certification within which to bring a civil action in Federal district court.

(3) The requestor must satisfy the requirements for venue under section 1869(b)(2)(C)(iii) of the Act, as well as the requirements for filing a civil action in a Federal district court under §405.1136(a) and §405.1136(c) through §405.1136(f).

(i) *Rejection of EAJR.* (1) If a request for EAJR request does not meet all the conditions set out in paragraphs (b), (c) and (d) of this section, or if the review entity does not certify a request for EAJR, the review entity advises in writing all parties that the request has been denied, and returns the request to the ALJ hearing office or the MAC, which will treat it as a request for hearing or for MAC review, as appropriate.

(2) Whenever a review entity forwards a rejected EAJR request to an ALJ hearing office or the MAC, the appeal is considered timely filed and the 90-day decision making time frame begins on the day the request is received by the hearing office or the MAC.

(j) *Interest on any amounts in controversy.* (1) If a provider or supplier is granted judicial review in accordance with this section, the amount in controversy, if any, is subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined in accordance with paragraphs (f)(4) or (h)(2) of this section, as applicable.

(2) The interest is awarded by the reviewing court and payable to a prevailing party.

(3) The rate of interest is equal to the rate of interest applicable to obligations issued for purchase by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this subpart is commenced.

(4) No interest awarded in accordance with this paragraph shall be income or cost for purposes of determining reimbursement due to providers or suppliers under Medicare.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005]

ALJ HEARINGS

§405.1000 Hearing before an ALJ: General rule.

(a) If a party is dissatisfied with a QIC's reconsideration or if the adjudication period specified in §405.970 for the QIC to complete its reconsideration has elapsed, the party may request a hearing.

(b) A hearing may be conducted in-person, by video-teleconference (VTC), or by telephone. At the hearing, the parties may submit evidence (subject to the restrictions in §405.1018 and §405.1028), examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, a representative of CMS or its contractor, including the QIC, QIO, fiscal intermediary or carrier, may participate in or join the hearing as a party. (*see* §405.1010 and §405.1012).

(d) The ALJ issues a decision based on the hearing record.

(e) If all parties to the hearing waive their right to appear at the hearing in

person or by telephone or video-teleconference, the ALJ may make a decision based on the evidence that is in the file and any new evidence that is submitted for consideration.

(f) The ALJ may require the parties to participate in a hearing if it is necessary to decide the case. If the ALJ determines that it is necessary to obtain testimony from a non-party, he or she may hold a hearing to obtain that testimony, even if all of the parties have waived the right to appear. In that event, however, the ALJ will give the parties the opportunity to appear when the testimony is given, but may hold the hearing even if none of the parties decide to appear.

(g) An ALJ may also issue a decision on the record on his or her own initiative if the evidence in the hearing record supports a fully favorable finding.

§ 405.1002 Right to an ALJ hearing.

(a) A party to a QIC reconsideration may request a hearing before an ALJ if—

(1) The party files a written request for an ALJ hearing within 60 days after receipt of the notice of the QIC's reconsideration.

(2) The party meets the amount in controversy requirements of § 405.1006.

(3) For purposes of this section, the date of receipt of the reconsideration is presumed to be 5 days after the date of the reconsideration, unless there is evidence to the contrary.

(4) For purposes of meeting the 60-day filing deadline, the request is considered as filed on the date it is received by the entity specified in the QIC's reconsideration.

(b) A party who files a timely appeal before a QIC and whose appeal continues to be pending before a QIC at the end of the period described in § 405.970 has a right to a hearing before an ALJ if—

(1) The party files a written request with the QIC to escalate the appeal to the ALJ level after the period described in § 405.970(a) and (b) has expired and the party files the request in accordance with § 405.970(d);

(2) The QIC does not issue a final action within 5 days of receiving the request for escalation in accordance with § 405.970(e)(2); and

(3) The party has an amount remaining in controversy specified in § 405.1006.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005]

§ 405.1004 Right to ALJ review of QIC notice of dismissal.

(a) A party to a QIC's dismissal of a request for reconsideration has a right to have the dismissal reviewed by an ALJ if—

(1) The party files a written request for an ALJ review within 60 days after receipt of the notice of the QIC's dismissal.

(2) The party meets the amount in controversy requirements of § 405.1006.

(3) For purposes of this section, the date of receipt of the QIC's dismissal is presumed to be 5 days after the date of the dismissal notice, unless there is evidence to the contrary.

(4) For purposes of meeting the 60-day filing deadline, the request is considered as filed on the date it is received by the entity specified in the QIC's dismissal.

(b) If the ALJ determines that the QIC's dismissal was in error, he or she vacates the dismissal and remands the case to the QIC for a reconsideration.

(c) An ALJ's decision regarding a QIC's dismissal of a reconsideration request is final and not subject to further review.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005]

§ 405.1006 Amount in controversy required to request an ALJ hearing and judicial review.

(a) *Definitions.* For the purposes of aggregating claims to meet the amount in controversy requirement for an ALJ hearing or judicial review:

(1) ''Common issues of law and fact'' means the claims sought to be aggregated are denied, or payment is reduced, for similar reasons and arise from a similar fact pattern material to the reason the claims are denied or payment is reduced.

(2) ''Delivery of similar or related services'' means like or coordinated services or items provided to one or more beneficiaries.

(b) *ALJ review.* To be entitled to a hearing before an ALJ, the party must meet the amount in controversy requirements of this section.

(1) For ALJ hearing requests, the required amount remaining in controversy must be $100 increased by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) as measured from July 2003 to the July preceding the current year involved.

(2) If the figure in paragraph (b)(1) of this section is not a multiple of $10, then it is rounded to the nearest multiple of $10. The Secretary will publish changes to the amount in controversy requirement in the FEDERAL REGISTER when necessary.

(c) *Judicial review.* To be entitled to judicial review, a party must meet the amount in controversy requirements of this subpart at the time it requests judicial review.

(1) For review requests, the required amount remaining in controversy must be $1,000 or more, adjusted as specified in paragraphs (b)(1) and (b)(2) of this section.

(2) [Reserved]

(d) *Calculating the amount remaining in controversy.* (1) The amount remaining in controversy is computed as the actual amount charged the individual for the items and services in question, reduced by—

(i) Any Medicare payments already made or awarded for the items or services; and

(ii) Any deductible and coinsurance amounts applicable in the particular case.

(2) Notwithstanding paragraph (d)(1) of this section, when payment is made for items or services under section 1879 of the Act or §411.400 of this chapter, or the liability of the beneficiary for those services is limited under §411.402 of this chapter, the amount in controversy is computed as the amount that the beneficiary would have been charged for the items or services in question if those expenses were not paid under §411.400 of this chapter or if that liability was not limited under §411.402 of this chapter, reduced by any deductible and coinsurance amounts applicable in the particular case.

(e) *Aggregating claims to meet the amount in controversy—*

(1) *Appealing QIC reconsiderations to the ALJ level.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

(i) The claims were previously reconsidered by a QIC;

(ii) The request for ALJ hearing lists all of the claims to be aggregated and is filed within 60 days after receipt of all of the reconsiderations being appealed; and

(iii) The ALJ determines that the claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

(2) *Aggregating claims that are escalated from the QIC level to the ALJ level.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

(i) The claims were pending before the QIC in conjunction with the same request for reconsideration;

(ii) The appellant(s) requests aggregation of the claims to the ALJ level in the same request for escalation; and

(iii) The ALJ determines that the claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

(f) *Content of request for aggregation.* When an appellant(s) seeks to aggregate claims in a request for an ALJ hearing, the appellant(s) must—

(1) Specify all of the claims the appellant(s) seeks to aggregate; and

(2) State why the appellant(s) believes that the claims involve common issues of law and fact or delivery of similar or related services.

§405.1008 Parties to an ALJ hearing.

(a) *Who may request a hearing.* Any party to the QIC's reconsideration may

request a hearing before an ALJ. However, only the appellant (that is, the party that filed and maintained the request for reconsideration by a QIC) may request that the appeal be escalated to the ALJ level if the QIC does not complete its action within the time frame described in § 405.970.

(b) *Who are parties to the ALJ hearing.* The party who filed the request for hearing and all other parties to the reconsideration are parties to the ALJ hearing. In addition, a representative of CMS or its contractor may be a party under the circumstances described in § 405.1012.

§ 405.1010 When CMS or its contractors may participate in an ALJ hearing.

(a) An ALJ may request, but may not require, CMS and/or one or more of its contractors, to participate in any proceedings before the ALJ, including the oral hearing, if any. CMS and/or one or more of its contractors, including a QIC, may also elect to participate in the hearing process.

(b) If CMS or one or more of its contractors elects to participate, it advises the ALJ, the appellant, and all other parties identified in the notice of hearing of its intent to participate no later than 10 days after receiving the notice of hearing.

(c) Participation may include filing position papers or providing testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of a party to the hearing.

(d) When CMS or its contractor participates in an ALJ hearing, the agency or its contractor may not be called as a witness during the hearing.

(e) CMS or its contractor must submit any position papers within the time frame designated by the ALJ.

(f) The ALJ cannot draw any adverse inferences if CMS or a contractor decides not to participate in any proceedings before an ALJ, including the hearing.

§ 405.1012 When CMS or its contractors may be a party to a hearing.

(a) CMS and/or one or more of its contractors, including a QIC, may be a party to an ALJ hearing unless the request for hearing is filed by an unrepresented beneficiary.

(b) CMS and/or the contractor(s) advises the ALJ, appellant, and all other parties identified in the notice of hearing that it intends to participate as a party no later than 10 days after receiving the notice of hearing.

(c) When CMS or one or more of its contractors participate in a hearing as a party, it may file position papers, provide testimony to clarify factual or policy issues, call witnesses or cross-examine the witnesses of other parties. CMS or its contractor(s) will submit any position papers within the time frame specified by the ALJ. CMS or its contractor(s), when acting as parties, may also submit additional evidence to the ALJ within the time frame designated by the ALJ.

(d) The ALJ may not require CMS or a contractor to enter a case as a party or draw any adverse inferences if CMS or a contractor decides not to enter as a party.

§ 405.1014 Request for an ALJ hearing.

(a) *Content of the request.* The request for an ALJ hearing must be made in writing. The request must include all of the following—

(1) The name, address, and Medicare health insurance claim number of the beneficiary whose claim is being appealed.

(2) The name and address of the appellant, when the appellant is not the beneficiary.

(3) The name and address of the designated representatives if any.

(4) The document control number assigned to the appeal by the QIC, if any.

(5) The dates of service.

(6) The reasons the appellant disagrees with the QIC's reconsideration or other determination being appealed.

(7) A statement of any additional evidence to be submitted and the date it will be submitted.

(b) *When and where to file.* The request for an ALJ hearing after a QIC reconsideration must be filed—

(1) Within 60 days from the date the party receives notice of the QIC's reconsideration;

(2) With the entity specified in the QIC's reconsideration. The appellant must also send a copy of the request

for hearing to the other parties. Failure to do so will toll the ALJ's 90-day adjudication deadline until all parties to the QIC reconsideration receive notice of the requested ALJ hearing. If the request for hearing is timely filed with an entity other than the entity specified in the QIC's reconsideration, the deadline specified in §405.1016 for deciding the appeal begins on the date the entity specified in the QIC's reconsideration receives the request for hearing. If the request for hearing is filed with an entity, other than the entity specified in the QIC's reconsideration, the ALJ hearing office must notify the appellant of the date of receipt of the request and the commencement of the 90-day adjudication time frame.

(c) *Extension of time to request a hearing.* (1) If the request for hearing is not filed within 60 calendar days of receipt of the QIC's reconsideration, an appellant may request an extension for good cause (*See* §§405.942(b)(2) and 405.942(b)(3)).

(2) Any request for an extension of time must be in writing, give the reasons why the request for a hearing was not filed within the stated time period, and must be filed with the entity specified in the notice of reconsideration.

(3) If the ALJ finds there is good cause for missing the deadline, the time period for filing the hearing request will be extended. To determine whether good cause for late filing exists, the ALJ uses the standards set forth in §405.942(b)(2) and §405.942(b)(3).

(4) If a request for hearing is not timely filed, the adjudication period in §405.1016 begins the date the ALJ grants the request to extend the filing deadline.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005]

§405.1016 Time frames for deciding an appeal before an ALJ.

(a) When a request for an ALJ hearing is filed after a QIC has issued a reconsideration, the ALJ must issue a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 90-day period beginning on the date the request for hearing is received by the entity specified in the QIC's notice of reconsideration, unless the 90-day period has been extended as provided in this subpart.

(b) The adjudication period specified in paragraph (a) of this section begins on the date that a timely filed request for hearing is received by the entity specified in the QIC's reconsideration, or, if it is not timely filed, the date that the ALJ grants any extension to the filing deadline.

(c) When an appeal is escalated to the ALJ level because the QIC has not issued a reconsideration determination within the period specified in §405.970, the ALJ must issue a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 180-day period beginning on the date that the request for escalation is received by the ALJ hearing office, unless the 180-day period is extended as provided in this subpart.

(d) When CMS or its contractor is a party to an ALJ hearing and a party requests discovery under §405.1037 against another party to the hearing, the adjudication periods discussed in paragraphs (a) and (c) of this section are tolled.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005]

§405.1018 Submitting evidence before the ALJ hearing.

(a) Except as provided in this section, parties must submit all written evidence they wish to have considered at the hearing with the request for hearing (or within 10 days of receiving the notice of hearing).

(b) If a party submits written evidence later than 10 days after receiving the notice of hearing, the period between the time the evidence was required to have been submitted and the time it is received is not counted toward the adjudication deadline specified in §405.1016.

(c) Any evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier that is not submitted prior to the issuance of the QIC's reconsideration determination must be accompanied by a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker (see §405.1028).

(d) The requirements of this section do not apply to oral testimony given at

a hearing, or to evidence submitted by an unrepresented beneficiary.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1020 Time and place for a hearing before an ALJ.

(a) *General.* The ALJ sets the time and place for the hearing, and may change the time and place, if necessary.

(b) *Determining how appearances are made.* The ALJ will direct that the appearance of an individual be conducted by videoteleconferencing (VTC) if the ALJ finds that VTC technology is available to conduct the appearance. The ALJ may also offer to conduct a hearing by telephone if the request for hearing or administrative record suggests that a telephone hearing may be more convenient for one or more of the parties. The ALJ, with the concurrence of the Managing Field Office ALJ, may determine that an in-person hearing should be conducted if—

(1) VTC technology is not available; or

(2) Special or extraordinary circumstances exist.

(c) *Notice of hearing.* (1) The ALJ sends a notice of hearing to all parties that filed an appeal or participated in the reconsideration, any party who was found liable for the services at issue subsequent to the initial determination, the contractor that issued the initial determination, and the QIC that issued the reconsideration, advising them of the proposed time and place of the hearing.

(2) The notice of hearing will require all parties to the ALJ hearing (and any potential participant from CMS or its contractor who wishes to attend the hearing) to reply to the notice by:

(i) Acknowledging whether they plan to attend the hearing at the time and place proposed in the notice of hearing; or

(ii) Objecting to the proposed time and/or place of the hearing.

(d) *A party's right to waive a hearing.* A party may also waive the right to a hearing and request that the ALJ issue a decision based on the written evidence in the record. As provided in § 405.1000, the ALJ may require the parties to attend a hearing if it is necessary to decide the case. If the ALJ determines that it is necessary to obtain testimony from a non-party, he or she may still hold a hearing to obtain that testimony, even if all of the parties have waived the right to appear. In those cases, the ALJ will give the parties the opportunity to appear when the testimony is given but may hold the hearing even if none of the parties decide to appear.

(e) *A party's objection to time and place of hearing.* (1) If a party objects to the time and place of the hearing, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing.

(2) The party must state the reason for the objection and state the time and place he or she wants the hearing to be held.

(3) The request must be in writing.

(4) The ALJ may change the time or place of the hearing if the party has good cause. (Section 405.1052(a)(2) provides the procedures the ALJ follows when a party does not respond to a notice of hearing and fails to appear at the time and place of the hearing.)

(f) *Good cause for changing the time or place.* The ALJ can find good cause for changing the time or place of the scheduled hearing and reschedule the hearing if the information available to the ALJ supports the party's contention that—

(1) The party or his or her representative is unable to attend or to travel to the scheduled hearing because of a serious physical or mental condition, incapacitating injury, or death in the family; or

(2) Severe weather conditions make it impossible to travel to the hearing; or

(3) Good cause exists as set forth in paragraph (g) of this section.

(g) *Good cause in other circumstances.* (1) In determining whether good cause exists in circumstances other than those set forth in paragraph (f) of this section, the ALJ considers the party's reason for requesting the change, the facts supporting the request, and the impact of the proposed change on the efficient administration of the hearing process.

(2) Factors evaluated to determine the impact of the change include, but

are not limited to, the effect on processing other scheduled hearings, potential delays in rescheduling the hearing, and whether any prior changes were granted the party.

(3) Examples of other circumstances a party might give for requesting a change in the time or place of the hearing include, but are not limited to, the following:

(i) The party has attempted to obtain a representative but needs additional time.

(ii) The party's representative was appointed within 10 days of the scheduled hearing and needs additional time to prepare for the hearing.

(iii) The party's representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing.

(iv) A witness who will testify to facts material to a party's case is unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained.

(v) Transportation is not readily available for a party to travel to the hearing.

(vi) The party is unrepresented, and is unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) that he or she has.

(h) *Effect of rescheduling hearing.* If a hearing is postponed at the request of the appellant for any of the above reasons, the time between the originally scheduled hearing date and the new hearing date is not counted toward the adjudication deadline specified in §405.1016.

(i) *A party's request for an in-person hearing.* (1) If a party objects to a VTC hearing or to the ALJ's offer to conduct a hearing by telephone, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request an in-person hearing.

(2) The party must state the reason for the objection and state the time or place he or she wants the hearing to be held.

(3) The request must be in writing.

(4) When a party's request for an in-person hearing is granted, the party is deemed to have waived the 90-day time frame specified in §405.1016.

(5) The ALJ may grant the request, with the concurrence of the Managing Field Office ALJ, upon a finding of good cause and will reschedule the hearing for a time and place when the party may appear in person before the ALJ.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§405.1022 Notice of a hearing before an ALJ.

(a) *Issuing the notice.* After the ALJ sets the time and place of the hearing, notice of the hearing will be mailed to the parties and other potential participants, as provided in §405.1020(c) at their last known addresses, or given by personal service, unless the parties have indicated in writing that they do not wish to receive this notice. The notice is mailed or served at least 20 days before the hearing.

(b) *Notice information.* (1) The notice of hearing contains a statement of the specific issues to be decided and will inform the parties that they may designate a person to represent them during the proceedings.

(2) The notice must include an explanation of the procedures for requesting a change in the time or place of the hearing, a reminder that, if the appellant fails to appear at the scheduled hearing without good cause, the ALJ may dismiss the hearing request, and other information about the scheduling and conduct of the hearing.

(3) The appellant will also be told if his or her appearance or that of any other party or witness is scheduled by VTC, telephone, or in person. If the ALJ has scheduled the appellant or other party to appear at the hearing by VTC, the notice of hearing will advise that the scheduled place for the hearing is a VTC site and explain what it means to appear at the hearing by VTC.

(4) The notice advises the appellant or other parties that if they object to appearing by VTC or telephone, and wish instead to have their hearing at a time and place where they may appear in person before the ALJ, they must follow the procedures set forth at §405.1020(i) for notifying the ALJ of

their objections and for requesting an in-person hearing.

(c) *Acknowledging the notice of hearing.* (1) If the appellant, any other party to the reconsideration, or their representative does not acknowledge receipt of the notice of hearing, the ALJ hearing office attempts to contact the party for an explanation.

(2) If the party states that he or she did not receive the notice of hearing, an amended notice is sent to him or her by certified mail or e-mail, if available. (See § 405.1052 for the procedures the ALJ follows in deciding if the time or place of a scheduled hearing will be changed if a party does not respond to the notice of hearing).

§ 405.1024 Objections to the issues.

(a) If a party objects to the issues described in the notice of hearing, he or she must notify the ALJ in writing at the earliest possible opportunity before the time set for the hearing, and no later than 5 days before the hearing.

(b) The party must state the reasons for his or her objections and send a copy of the objections to all other parties to the appeal.

(c) The ALJ makes a decision on the objections either in writing or at the hearing.

§ 405.1026 Disqualification of the ALJ.

(a) An ALJ cannot conduct a hearing if he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) If a party objects to the ALJ who will conduct the hearing, the party must notify the ALJ within 10 calendar days of the date of the notice of hearing. The ALJ considers the party's objections and decides whether to proceed with the hearing or withdraw.

(c) If the ALJ withdraws, another ALJ will be appointed to conduct the hearing. If the ALJ does not withdraw, the party may, after the ALJ has issued an action in the case, present his or her objections to the MAC in accordance with § 405.1100 *et seq.* The MAC will then consider whether the hearing decision should be revised or a new hearing held before another ALJ. If the case is escalated to the MAC after a hearing is held but before the ALJ issues a decision, the MAC considers the reasons the party objected to the ALJ during its review of the case and, if the MAC deems it necessary, may remand the case to another ALJ for a hearing and decision.

§ 405.1028 Prehearing case review of evidence submitted to the ALJ.

(a) *Examination of any new evidence.* After a hearing is requested but before it is held, the ALJ will examine any new evidence submitted with the request for hearing (or within 10 days of receiving the notice of hearing) as specified in § 405.1018, by a provider, supplier, or beneficiary represented by a provider or supplier to determine whether the provider, supplier, or beneficiary represented by a provider or supplier had good cause for submitting the evidence for the first time at the ALJ level.

(b) *Determining if good cause exists.* An ALJ finds good cause, for example, when the new evidence is material to an issue addressed in the QIC's reconsideration and that issue was not identified as a material issue prior to the QIC's reconsideration.

(c) *If good cause does not exist.* If the ALJ determines that there was not good cause for submitting the evidence for the first time at the ALJ level, the ALJ must exclude the evidence from the proceeding and may not consider it in reaching a decision.

(d) *Notification to all parties.* As soon as possible, but no later than the start of the hearing, the ALJ must notify all parties that the evidence is excluded from the hearing.

§ 405.1030 ALJ hearing procedures.

(a) *General rule.* A hearing is open to the parties and to other persons the ALJ considers necessary and proper.

(b) *At the hearing.* At the hearing, the ALJ fully examines the issues, questions the parties and other witnesses, and may accept documents that are material to the issues consistent with § 405.1018 and § 405.1028.

(c) *Missing evidence.* The ALJ may also stop the hearing temporarily and continue it at a later date if he or she believes that there is material evidence missing at the hearing. If the missing evidence is in the possession of the appellant, and the appellant is a provider,

supplier, or a beneficiary represented by a provider or supplier, the ALJ must determine if the appellant had good cause for not producing the evidence earlier.

(d) *Good cause exists.* If good cause exists, the ALJ considers the evidence in deciding the case and the adjudication period specified in §405.1016 is tolled from the date of the hearing to the date the evidence is submitted.

(e) *Good cause does not exist.* If the ALJ determines that there was not good cause for not submitting the evidence sooner, the evidence is excluded.

(f) *Reopen the hearing.* The ALJ may also reopen the hearing at any time before he or she mails a notice of the decision in order to receive new and material evidence pursuant to §405.986. The ALJ may decide when the evidence is presented and when the issues are discussed.

§405.1032 Issues before an ALJ.

(a) *General rule.* The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. (For purposes of this provision, the term ''party'' does not include a representative of CMS or one of its contractors that may be participating in the hearing.) However, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, he or she notifies the parties before the hearing and may consider it an issue at the hearing.

(b) *New issues*—(1) *General.* The ALJ may consider a new issue at the hearing if he or she notifies all of the parties about the new issue any time before the start of the hearing. The new issue may include issues resulting from the participation of CMS at the ALJ level of adjudication and from any evidence and position papers submitted by CMS for the first time to the ALJ. The ALJ or any party may raise a new issue; however, the ALJ may only consider a new issue if its resolution—

(i) Could have a material impact on the claim or claims that are the subject of the request for hearing; and

(ii) Is permissible under the rules governing reopening of determinations and decisions (see §405.980).

(2) [Reserved]

(c) *Adding claims to a pending appeal.* An ALJ cannot add any claim, including one that is related to an issue that is appropriately before an ALJ, to a pending appeal unless it has been adjudicated at the lower appeals levels and all parties are notified of the new issue(s) before the start of the hearing.

§405.1034 When an ALJ may remand a case to the QIC.

(a) *General.* If an ALJ believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS or its contractors, then the ALJ may either:

(1) Remand the case to the QIC that issued the reconsideration or

(2) Retain jurisdiction of the case and request that the contractor forward the missing information to the appropriate hearing office.

(b) *ALJ remands a case to a QIC.* Consistent with §405.1004 (b), the ALJ will remand a case to the appropriate QIC if the ALJ determines that a QIC's dismissal of a request for reconsideration was in error.

(c) *Relationship to local and national coverage determination appeals process.* (1) The ALJ remands an appeal to the QIC that made the reconsideration if the appellant is entitled to relief pursuant to 42 CFR 426.460(b)(1), 426.488(b), or 426.560(b)(1).

(2) Unless the appellant is entitled to relief pursuant to 42 CFR 426.460(b)(1), 426.488(b), or 426.560(b)(1), the ALJ applies the LCD or NCD in place on the date the item or service was provided.

§405.1036 Description of an ALJ hearing process.

(a) *The right to appear and present evidence.* (1) Any party to a hearing has the right to appear before the ALJ to present evidence and to state his or her position. A party may appear by video-teleconferencing (VTC), telephone, or in person as determined under §405.1020.

(2) A party may also make his or her appearance by means of a representative, who may make the appearance by VTC, telephone, or in person, as determined under §405.1020.

(3) Witness testimony may be given and CMS participation may also be accomplished by VTC, telephone, or in person, as determined under § 405.1020.

(b) *Waiver of the right to appear.* (1) A party may send the ALJ a written statement indicating that he or she does not wish to appear at the hearing.

(2) The appellant may subsequently withdraw his or her waiver at any time before the notice of the hearing decision is issued; however, by withdrawing the waiver the appellant agrees to an extension of the adjudication period as specified in § 405.1016 that may be necessary to schedule and hold the hearing.

(3) Other parties may withdraw their waiver up to the date of the scheduled hearing, if any. Even if all of the parties waive their right to appear at a hearing, the ALJ may require them to attend an oral hearing if he or she believes that a personal appearance and testimony by the appellant or any other party is necessary to decide the case.

(c) *Presenting written statements and oral arguments.* A party or a person designated to act as a party's representative may appear before the ALJ to state the party's case, to present a written summary of the case, or to enter written statements about the facts and law material to the case in the record. A copy of any written statements must be provided to the other parties to a hearing, if any, at the same time they are submitted to the ALJ.

(d) *Waiver of adjudication period.* At any time during the hearing process, the appellant may waive the adjudication deadline specified in § 405.1016 for issuing a hearing decision. The waiver may be for a specific period of time agreed upon by the ALJ and the appellant.

(e) *What evidence is admissible at a hearing.* The ALJ may receive evidence at the hearing even though the evidence is not admissible in court under the rules of evidence used by the court.

(f) *Subpoenas.* (1) When it is reasonably necessary for the full presentation of a case, an ALJ may, on his or her own initiative or at the request of a party, issue subpoenas for the appearance and testimony of witnesses and for a party to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying.

(2) A party's written request for a subpoena must—

(i) Give the names of the witnesses or documents to be produced;

(ii) Describe the address or location of the witnesses or documents with sufficient detail to find them;

(iii) State the important facts that the witness or document is expected to prove; and

(iv) Indicate why these facts cannot be proven without issuing a subpoena.

(3) Parties to a hearing who wish to subpoena documents or witnesses must file a written request for the issuance of a subpoena with the requirements set out in paragraph (f)(2) of this section with the ALJ within 10 calendar days of receipt of the notice of hearing.

(4) Where a party has requested a subpoena, a subpoena will be issued only where a party—

(i) Has sought discovery;

(ii) Has filed a motion to compel;

(iii) Has had that motion granted by the ALJ; and

(iv) Nevertheless, has not received the requested discovery.

(5) Reviewability of subpoena rulings—

(i) *General rule.* An ALJ ruling on a subpoena request is not subject to immediate review by the MAC. The ruling may be reviewed solely during the course of the MAC's review specified in § 405.1102, § 405.1104, or § 405.1110, as applicable. *Exception.* To the extent a subpoena compels disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before an ALJ, the MAC may review immediately the subpoena or that portion of the subpoena as applicable.

(ii) Where CMS objects to a discovery ruling, the MAC must take review and the discovery ruling at issue is automatically stayed pending the MAC's order.

(iii) Upon notice to the ALJ that a party or non-party, as applicable, intends to seek MAC review of the subpoena, the ALJ must stay all proceedings affected by the subpoena.

(iv) The ALJ determines the length of the stay under the circumstances of a given case, but in no event is the stay less than 15 days beginning after the day on which the ALJ received notice of the party or non-party's intent to seek MAC review.

(v) If the MAC grants a request for review of the subpoena, the subpoena or portion of the subpoena, as applicable, is stayed until the MAC issues a written decision that affirms, reverses, or modifies the ALJ's action on the subpoena.

(vi) If the MAC does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the ALJ's action stands.

(6) Enforcement. (i) If the ALJ determines, whether on his or her own motion or at the request of a party, that a party or non-party subject to a subpoena issued under this section has refused to comply with the subpoena, the ALJ may request the Secretary to seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(ii) Any enforcement request by an ALJ must consist of a written notice to the Secretary describing in detail the ALJ's findings of noncompliance and his or her specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the party or nonparty subject to the subpoena.

(iii) The ALJ must promptly mail a copy of the notice and related documents to the party subject to the subpoena, and to any other party and affected non-party to the appeal.

(g) *Witnesses at a hearing.* Witnesses may appear at a hearing. They testify under oath or affirmation, unless the ALJ finds an important reason to excuse them from taking an oath or affirmation. The ALJ may ask the witnesses any questions relevant to the issues and allows the parties or their designated representatives to do so.

§405.1037 Discovery.

(a) *General rules.* (1) Discovery is permissible only when CMS or its contractor elects to participate in an ALJ hearing as a party.

(2) The ALJ may permit discovery of a matter that is relevant to the specific subject matter of the ALJ hearing, provided the matter is not privileged or otherwise protected from disclosure and the ALJ determines that the discovery request is not unreasonable, unduly burdensome or expensive, or otherwise inappropriate.

(3) Any discovery initiated by a party must comply with all requirements and limitations of this section, along with any further requirements or limitations ordered by the ALJ.

(b) *Limitations on discovery.* Any discovery before the ALJ is limited.

(1) A party may request of another party the reasonable production of documents for inspection and copying.

(2) A party may not take the deposition, upon oral or written examination, of another party unless the proposed deponent agrees to the deposition or the ALJ finds that the proposed deposition is necessary and appropriate in order to secure the deponent's testimony for an ALJ hearing.

(3) A party may not request admissions or send interrogatories or take any other form of discovery not permitted under this section.

(c) *Time limits.* (1) A party's discovery request is timely if the date of receipt of a request by another party is no later than the date specified by the ALJ.

(2) A party may not conduct discovery any later than the date specified by the ALJ.

(3) Before ruling on a request to extend the time for requesting discovery or for conducting discovery, the ALJ must give the other parties to the appeal a reasonable period to respond to the extension request.

(4) The ALJ may extend the time in which to request discovery or conduct discovery only if the requesting party establishes that it was not dilatory or otherwise at fault in not meeting the original discovery deadline.

(5) If the ALJ grants the extension request, it must impose a new discovery deadline and, if necessary, reschedule the hearing date so that all discoveries end no later than 45 days before the hearing.

(d) *Motions to compel or for protective order.* (1) Each party is required to make a good faith effort to resolve or narrow any discovery dispute.

(2) A party may submit to the ALJ a motion to compel discovery that is permitted under this section or any ALJ order, and a party may submit a motion for a protective order regarding any discovery request to the ALJ.

(3) Any motion to compel or for protective order must include a self-sworn declaration describing the movant's efforts to resolve or narrow the discovery dispute. The declaration must also be included with any response to a motion to compel or for protective order.

(4) The ALJ must decide any motion in accordance with this section and any prior discovery ruling in the appeal.

(5) The ALJ must issue and mail to each party a discovery ruling that grants or denies the motion to compel or for protective order in whole or in part; if applicable, the discovery ruling must specifically identify any part of the disputed discovery request upheld and any part rejected, and impose any limits on discovery the ALJ finds necessary and appropriate.

(e) *Reviewability of discovery and disclosure rulings—*

(1) *General rule.* An ALJ discovery ruling, or an ALJ disclosure ruling such as one issued at a hearing is not subject to immediate review by the MAC. The ruling may be reviewed solely during the course of the MAC's review specified in § 405.1100, § 405.1102, § 405.1104, or § 405.1110, as applicable.

(2) *Exception.* To the extent a ruling authorizes discovery or disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the ALJ, the MAC may review that portion of the discovery or disclosure ruling immediately.

(i) Where CMS objects to a discovery ruling, the MAC must take review and the discovery ruling at issue is automatically stayed pending the MAC's order.

(ii) Upon notice to the ALJ that a party intends to seek MAC review of the ruling, the ALJ must stay all proceedings affected by the ruling.

(iii) The ALJ determines the length of the stay under the circumstances of a given case, but in no event must the length of the stay be less than 15 days beginning after the day on which the ALJ received notice of the party or non-party's intent to seek MAC review.

(iv) Where CMS requests the MAC to take review of a discovery ruling or where the MAC grants a request, made by a party other than CMS, to review a discovery ruling, the ruling is stayed until the time the MAC issues a written decision that affirms, reverses, modifies, or remands the ALJ's ruling.

(v) With respect to a request from a party, other than CMS, for review of a discovery ruling, if the MAC does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the ruling stands.

(f) *Adjudication time frames.* If a party requests discovery from another party to the ALJ hearing, the ALJ adjudication time frame specified in § 405.1016 is tolled until the discovery dispute is resolved.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1038 Deciding a case without a hearing before an ALJ.

(a) *Decision wholly favorable.* If the evidence in the hearing record supports a finding in favor of appellant(s) on every issue, the ALJ may issue a hearing decision without giving the parties prior notice and without holding a hearing. The notice of the decision informs the parties that they have the right to a hearing and a right to examine the evidence on which the decision is based.

(b) *Parties do not wish to appear.* (1) The ALJ may decide a case on the record and not conduct a hearing if—

(i) All the parties indicate in writing that they do not wish to appear before the ALJ at a hearing, including a hearing conducted by telephone or videoconferencing, if available; or

(ii) The appellant lives outside the United States and does not inform the ALJ that he or she wants to appear, and there are no other parties who wish to appear.

(2) When a hearing is not held, the decision of the ALJ must refer to the evidence in the record on which the decision was based.

§405.1040 Prehearing and posthearing conferences.

(a) The ALJ may decide on his or her own, or at the request of any party to the hearing, to hold a prehearing or posthearing conference to facilitate the hearing or the hearing decision.

(b) The ALJ informs the parties of the time, place, and purpose of the conference at least 7 calendar days before the conference date, unless a party indicates in writing that it does not wish to receive a written notice of the conference.

(c) At the conference, the ALJ may consider matters in addition to those stated in the notice of hearing, if the parties consent in writing. A record of the conference is made.

(d) The ALJ issues an order stating all agreements and actions resulting from the conference. If the parties do not object, the agreements and actions become part of the hearing record and are binding on all parties.

§405.1042 The administrative record.

(a) *Creating the record.* (1) The ALJ makes a complete record of the evidence, including the hearing proceedings, if any.

(2) The record will include marked as exhibits, the documents used in making the decision under review, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ admits. In the record, the ALJ must also discuss any evidence excluded under §405.1028 and include a justification for excluding the evidence.

(3) A party may review the record at the hearing, or, if a hearing is not held, at any time before the ALJ's notice of decision is issued.

(4) If a request for review is filed or the case is escalated to the MAC, the complete record, including any recording of the hearing, is forwarded to the MAC.

(5) A typed transcription of the hearing is prepared if a party seeks judicial review of the case in a Federal district court within the stated time period and all other jurisdictional criteria are met, unless, upon the Secretary's motion prior to the filing of an answer, the court remands the case.

(b) *Requesting and receiving copies of the record.* (1) A party may request and receive a copy of all or part of the record, including the exhibits list, documentary evidence, and a copy of the tape of the oral proceedings. The party may be asked to pay the costs of providing these items.

(2) If a party requests all or part of the record from the ALJ and an opportunity to comment on the record, the time beginning with the ALJ's receipt of the request through the expiration of the time granted for the party's response does not count toward the 90-day adjudication deadline.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§405.1044 Consolidated hearing before an ALJ.

(a) A consolidated hearing may be held if one or more of the issues to be considered at the hearing are the same issues that are involved in another request for hearing or hearings pending before the same ALJ.

(b) It is within the discretion of the ALJ to grant or deny an appellant's request for consolidation. In considering an appellant's request, the ALJ may consider factors such as whether the claims at issue may be more efficiently decided if the requests for hearing are combined. In considering the appellant's request for consolidation, the ALJ must take into account the adjudication deadlines for each case and may require an appellant to waive the adjudication deadline associated with one or more cases if consolidation otherwise prevents the ALJ from deciding all of the appeals at issue within their respective deadlines.

(c) The ALJ may also propose on his or her own motion to consolidate two

or more cases in one hearing for administrative efficiency, but may not require an appellant to waive the adjudication deadline for any of the consolidated cases.

(d) Before consolidating a hearing, the ALJ must notify CMS of his or her intention to do so, and CMS may then elect to participate in the consolidated hearing, as a party, by sending written notice to the ALJ within 10 days after receipt of the ALJ's notice of the consolidation.

(e) If the ALJ decides to hold a consolidated hearing, he or she may make either a consolidated decision and record or a separate decision and record on each claim. The ALJ ensures that any evidence that is common to all claims and material to the common issue to be decided is included in the consolidated record or each individual record, as applicable.

§ 405.1046 Notice of an ALJ decision.

(a) *General rule.* Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. The decision must be based on evidence offered at the hearing or otherwise admitted into the record. The ALJ mails a copy of the decision to all the parties at their last known address, to the QIC that issued the reconsideration determination, and to the contractor that issued the initial determination. For overpayment cases involving multiple beneficiaries, where there is no beneficiary liability, the ALJ may choose to send written notice only to the appellant. In the event a payment will be made to a provider or supplier in conjunction with this ALJ decision, the contractor must also issue a revised electronic or paper remittance advice to that provider or supplier.

(b) *Content of the notice.* The decision must be written in a manner calculated to be understood by a beneficiary and must include—

(1) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination;

(2) The procedures for obtaining additional information concerning the decision; and

(3) Notification of the right to appeal the decision to the MAC, including instructions on how to initiate an appeal under this section.

(c) *Limitation on decision.* When the amount of payment for an item or service is an issue before the ALJ, the ALJ may make a finding as to the amount of payment due. If the ALJ makes a finding concerning payment when the amount of payment was not an issue before the ALJ, the contractor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's decision is not final for purposes of determining the amount of payment due. The amount of payment determined by the contractor in effectuating the ALJ's decision is a new initial determination under § 405.924.

(d) *Timing of decision.* The ALJ issues a decision by the end of the 90-day period beginning on the date when the request for hearing is received by the entity specified in the QIC's reconsideration, unless the 90-day period is extended as provided in § 405.1016.

(e) *Recommended decision.* An ALJ issues a recommended decision if he or she is directed to do so in the MAC's remand order. An ALJ may not issue a recommended decision on his or her own motion. The ALJ mails a copy of the recommended decision to all the parties at their last known address.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1048 The effect of an ALJ's decision.

The decision of the ALJ is binding on all parties to the hearing unless—

(a) A party to the hearing requests a review of the decision by the MAC within the stated time period or the MAC reviews the decision issued by an ALJ under the procedures set forth in § 405.1110, and the MAC either issues a final action or the appeal is escalated to Federal district court under the provisions at § 405.1132 and the Federal district court issues a decision.

(b) The decision is reopened and revised by an ALJ or the MAC under the procedures explained in § 405.980;

(c) The expedited access to judicial review process at §405.990 is used;

(d) The ALJ's decision is a recommended decision directed to the MAC and the MAC issues a decision; or

(e) In a case remanded by a Federal district court, the MAC assumes jurisdiction under the procedures in §405.1138 and the MAC issues a decision.

§405.1050 Removal of a hearing request from an ALJ to the MAC.

If a request for hearing is pending before an ALJ, the MAC may assume responsibility for holding a hearing by requesting that the ALJ send the hearing request to it. If the MAC holds a hearing, it conducts the hearing according to the rules for hearings before an ALJ. Notice is mailed to all parties at their last known address informing them that the MAC has assumed responsibility for the case.

§405.1052 Dismissal of a request for a hearing before an ALJ.

Dismissal of a request for a hearing is in accordance with the following:

(a) An ALJ dismisses a request for a hearing under any of the following conditions:

(1) At any time before notice of the hearing decision is mailed, if only one party requested the hearing and that party asks to withdraw the request. This request may be submitted in writing to the ALJ or made orally at the hearing. The request for withdrawal must include a clear statement that the appellant is withdrawing the request for hearing and does not intend to further proceed with the appeal. If an attorney, or other legal professional on behalf of a beneficiary or other appellant files the request for withdrawal, the ALJ may presume that the representative has advised the appellant of the consequences of the withdrawal and dismissal.

(2) Neither the party that requested the hearing nor the party's representative appears at the time and place set for the hearing, if—

(i) The party was notified before the time set for the hearing that the request for hearing might be dismissed without further notice for failure to appear;

(ii) The party did not appear at the time and place of hearing and does not contact the ALJ hearing office within 10 days and provide good cause for not appearing; or

(iii) The ALJ sends a notice to the party asking why the party did not appear; and the party does not respond to the ALJ's notice within 10 days or does not provide good cause for the failure to appear.

(iv) In determining whether good cause exists under this paragraph (a)(2), the ALJ considers any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language), that the party may have.

(3) The person or entity requesting a hearing has no right to it under §405.1002.

(4) The party did not request a hearing within the stated time period and the ALJ has not found good cause for extending the deadline, as provided in §405.1014(c).

(5) The beneficiary whose claim is being appealed died while the request for hearing is pending and all of the following criteria apply:

(i) The request for hearing was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the ALJ considers if the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation of liability provisions based on the denial of the services at issue.

(ii) No other individuals or entities that have a financial interest in the case wish to pursue an appeal under §405.1002.

(iii) No other individual or entity filed a valid and timely request for an ALJ hearing in accordance to §405.1014.

(6) The ALJ dismisses a hearing request entirely or refuses to consider any one or more of the issues because a QIC, an ALJ or the MAC has made a previous determination or decision under this subpart about the appellant's rights on the same facts and on the same issue(s) or claim(s), and this previous determination or decision has

become final by either administrative or judicial action.

(7) The appellant abandons the request for hearing. An ALJ may conclude that an appellant has abandoned a request for hearing when the ALJ hearing office attempts to schedule a hearing and is unable to contact the appellant after making reasonable efforts to do so.

(b) *Notice of dismissal.* The ALJ mails a written notice of the dismissal of the hearing request to all parties at their last known address. The notice states that there is a right to request that the MAC vacate the dismissal action.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1054 Effect of dismissal of a request for a hearing before an ALJ.

The dismissal of a request for a hearing is binding, unless it is vacated by the MAC under § 405.1108(b).

APPLICABILITY OF MEDICARE COVERAGE POLICIES

§ 405.1060 Applicability of national coverage determinations (NCDs).

(a) *General rule.* (1) An NCD is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare.

(2) An NCD does not include a determination of what code, if any, is assigned to a particular item or service covered under Medicare or a determination of the amount of payment made for a particular item or service.

(3) NCDs are made under section 1862(a)(1) of the Act as well as under other applicable provisions of the Act.

(4) An NCD is binding on fiscal intermediaries, carriers, QIOs, QICs, ALJs, and the MAC.

(b) *Review by an ALJ.* (1) An ALJ may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim.

(c) *Review by the MAC.* (1) The MAC may not disregard, set aside, or otherwise review an NCD for purposes of a section 1869 claim appeal, except that the DAB may review NCDs as provided under part 426 of this title.

(2) The MAC may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1062 Applicability of local coverage determinations and other policies not binding on the ALJ and MAC.

(a) ALJs and the MAC are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

(b) If an ALJ or MAC declines to follow a policy in a particular case, the ALJ or MAC decision must explain the reasons why the policy was not followed. An ALJ or MAC decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

(c) An ALJ or MAC may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. An ALJ or the DAB may review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 of this title.

§ 405.1063 Applicability of CMS Rulings.

CMS Rulings are published under the authority of the Administrator, CMS. Consistent with § 401.108 of this chapter, rulings are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

§ 405.1064 ALJ decisions involving statistical samples.

When an appeal from the QIC involves an overpayment issue and the QIC used a statistical sample in reaching its reconsideration, the ALJ must base his or her decision on a review of

the entire statistical sample used by the QIC.

MEDICARE APPEALS COUNCIL REVIEW

§405.1100 Medicare Appeals Council review: General.

(a) The appellant or any other party to the hearing may request that the MAC review an ALJ's decision or dismissal.

(b) Under circumstances set forth in §405.1104 and 405.1108, the appellant may request that a case be escalated to the MAC for a decision even if the ALJ has not issued a decision or dismissal in his or her case.

(c) When the MAC reviews an ALJ's decision, it undertakes a de novo review. The MAC issues a final action or remands a case to the ALJ within 90 days of receipt of the appellant's request for review, unless the 90-day period is extended as provided in this subpart.

(d) When deciding an appeal that was escalated from the ALJ level to the MAC, the MAC will issue a final action or remand the case to the ALJ within 180 days of receipt of the appellant's request for escalation, unless the 180-day period is extended as provided in this subpart.

§405.1102 Request for MAC review when ALJ issues decision or dismissal.

(a)(1) A party to the ALJ hearing may request a MAC review if the party files a written request for a MAC review within 60 days after receipt of the ALJ's decision or dismissal.

(2) For purposes of this section, the date of receipt of the ALJ's decision or dismissal is presumed to be 5 days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

(3) The request is considered as filed on the date it is received by the entity specified in the notice of the ALJ's action.

(b) A party requesting a review may ask that the time for filing a request for MAC review be extended if—

(1) The request for an extension of time is in writing;

(2) It is filed with the MAC; and

(3) It explains why the request for review was not filed within the stated time period. If the MAC finds that there is good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the MAC uses the standards outlined at §§405.942(b)(2) and 405.942(b)(3).

(c) A party does not have the right to seek MAC review of an ALJ's remand to a QIC or an ALJ's affirmation of a QIC's dismissal of a request for reconsideration.

(d) For purposes of requesting MAC review (§405.1100 through §405.1140), unless specifically excepted the term, ''party,'' includes CMS where CMS has entered into a case as a party according to §405.1012. The term, ''appellant,'' does not include CMS, where CMS has entered into a case as a party according to §405.1012.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§405.1104 Request for MAC review when an ALJ does not issue a decision timely.

(a) *Requesting escalation.* An appellant who files a timely request for hearing before an ALJ and whose appeal continues to be pending before the ALJ at the end of the applicable ALJ adjudication period under §405.1016 may request MAC review if—

(1) The appellant files a written request with the ALJ to escalate the appeal to the MAC after the adjudication period has expired; and

(2) The ALJ does not issue a final action or remand the case to the QIC within the later of 5 days of receiving the request for escalation or 5 days from the end of the applicable adjudication period set forth in §405.1016.

(b) *Escalation.* (1) If the ALJ is not able to issue a final action or remand within the time period set forth in paragraph (a)(2) of this section, he or she sends notice to the appellant.

(2) The notice acknowledges receipt of the request for escalation, and confirms that the ALJ is not able to issue a final action or remand order within the statutory time frame.

(3) If the ALJ does not act on a request for escalation within the time period set forth in paragraph (a)(2) of this section or does not send the required

notice to the appellant, the QIC decision becomes a final administrative decision for purposes of MAC review.

(c) *No escalation.* If the ALJ's adjudication period set forth in §405.1016 expires, the case remains with the ALJ until a final action is issued or the appellant requests escalation to the MAC.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1106 Where a request for review or escalation may be filed.

(a) When a request for a MAC review is filed after an ALJ has issued a decision or dismissal, the request for review must be filed with the entity specified in the notice of the ALJ's action. The appellant must also send a copy of the request for review to the other parties to the ALJ decision or dismissal. Failure to copy the other parties tolls the MAC's adjudication deadline set forth in §405.1100 until all parties to the hearing receive notice of the request for MAC review. If the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's action, the MAC's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's action. Upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's action, the MAC sends written notice to the appellant of the date of receipt of the request and commencement of the adjudication time frame.

(b) If an appellant files a request to escalate an appeal to the MAC level because the ALJ has not completed his or her action on the request for hearing within the adjudication deadline under §405.1016, the request for escalation must be filed with both the ALJ and the MAC. The appellant must also send a copy of the request for escalation to the other parties. Failure to copy the other parties tolls the MAC's adjudication deadline set forth in §405.1100 until all parties to the hearing receive notice of the request for MAC review. In a case that has been escalated from the ALJ, the MAC's 180-day period to issue a final action or remand the case to the ALJ begins on the date the request for escalation is received by the MAC.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1108 MAC actions when request for review or escalation is filed.

(a) Except as specified in paragraphs (c) and (d) of this section, when a party requests that the MAC review an ALJ's decision, the MAC will review the ALJ's decision *de novo.* The party requesting review does not have a right to a hearing before the MAC. The MAC will consider all of the evidence in the administrative record. Upon completion of its review, the MAC may adopt, modify, or reverse the ALJ's decision or remand the case to an ALJ for further proceedings.

(b) When a party requests that the MAC review an ALJ's dismissal, the MAC may deny review or vacate the dismissal and remand the case to the ALJ for further proceedings.

(c) The MAC will dismiss a request for review when the party requesting review does not have a right to a review by the MAC, or will dismiss the request for a hearing for any reason that the ALJ could have dismissed the request for hearing.

(d) When an appellant requests escalation of a case from the ALJ level to the MAC, the MAC may take any of the following actions:

(1) Issue a decision based on the record constructed at the QIC and any additional evidence, including oral testimony, entered in the record by the ALJ before the case was escalated.

(2) Conduct any additional proceedings, including a hearing, that the MAC determines are necessary to issue a decision.

(3) Remand the case to an ALJ for further proceedings, including a hearing.

(4) Dismiss the request for MAC review because the appellant does not have the right to escalate the appeal.

(5) Dismiss the request for a hearing for any reason that the ALJ could have dismissed the request.

§ 405.1110 MAC reviews on its own motion.

(a) *General rule.* The MAC may decide on its own motion to review a decision

or dismissal issued by an ALJ. CMS or any of its contractors may refer a case to the MAC for it to consider reviewing under this authority anytime within 60 days after the date of an ALJ's decision or dismissal.

(b) *Referral of cases.* (1) CMS or any of its contractors may refer a case to the MAC if, in their view, the decision or dismissal contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest. CMS may also request that the MAC take own motion review of a case if—

(i) CMS or its contractor participated in the appeal at the ALJ level; and

(ii) In CMS' view, the ALJ's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ abused his or her discretion.

(2) CMS's referral to the MAC is made in writing and must be filed with the MAC no later than 60 days after the ALJ's decision or dismissal is issued. The written referral will state the reasons why CMS believes that the MAC must review the case on its own motion. CMS will send a copy of its referral to all parties to the ALJ's action and to the ALJ. Parties to the ALJ's action may file exceptions to the referral by submitting written comments to the MAC within 20 days of the referral notice. A party submitting comments to the MAC must send such comments to CMS and all other parties to the ALJ's decision.

(c) *Standard of review.* (1) Referral by CMS after participation at the ALJ level. If CMS or its contractor participated in an appeal at the ALJ level, the MAC exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the MAC will limit its consideration of the ALJ's action to those exceptions raised by CMS.

(2) *Referral by CMS when CMS did not participate in the ALJ proceedings or appear as a party.* The MAC will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the MAC will limit its consideration of the ALJ's action to those exceptions raised by CMS.

(d) *MAC's action.* If the MAC decides to review a decision or dismissal on its own motion, it will mail the results of its action to all the parties to the hearing and to CMS if it is not already a party to the hearing. The MAC may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ for further proceedings or may dismiss a hearing request. The MAC must issue its action no later than 90 days after receipt of the CMS referral, unless the 90-day period has been extended as provided in this subpart. The MAC may not, however, issue its action before the 20-day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case. If the MAC does not act within the applicable adjudication deadline, the ALJ's decision or dismissal remains the final action in the case.

§405.1112 Content of request for review.

(a) The request for MAC review must be filed with the MAC or appropriate ALJ hearing office. The request for review must be in writing and may be made on a standard form. A written request that is not made on a standard form is accepted if it contains the beneficiary's name; Medicare health insurance claim number; the specific service(s) or item(s) for which the review is requested; the specific date(s) of service; the date of the ALJ's final action, if any, if the party is requesting escalation from the ALJ to the MAC, the hearing office in which the appellant's request for hearing is pending; and the name and signature of the party or the representative of the party; and any other information CMS may decide.

(b) The request for review must identify the parts of the ALJ action with

which the party requesting review disagrees and explain why he or she disagrees with the ALJ's decision, dismissal, or other determination being appealed. For example, if the party requesting review believes that the ALJ's action is inconsistent with a statute, regulation, CMS Ruling, or other authority, the request for review should explain why the appellant believes the action is inconsistent with that authority.

(c) The MAC will limit its review of an ALJ's actions to those exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. For purposes of this section only, we define a representative as anyone who has accepted an appointment as the beneficiary's representative, except a member of the beneficiary's family, a legal guardian, or an individual who routinely acts on behalf of the beneficiary, such as a family member or friend who has a power of attorney.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1114 Dismissal of request for review.

The MAC dismisses a request for review if the party requesting review did not file the request within the stated period of time and the time for filing has not been extended. The MAC also dismisses the request for review if—

(a) The party asks to withdraw the request for review;

(b) The party does not have a right to request MAC review; or

(c) The beneficiary whose claim is being appealed died while the request for review is pending and all of the following criteria apply:

(1) The request for review was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the MAC considers whether the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation of liability provisions based on the denial of the services at issue;

(2) No other individual or entity with a financial interest in the case wishes to pursue an appeal under § 405.1102;

(3) No other party to the ALJ hearing filed a valid and timely review request under § 405.1102 and § 405.1112.

§ 405.1116 Effect of dismissal of request for MAC review or request for hearing.

The dismissal of a request for MAC review or denial of a request for review of a dismissal issued by an ALJ is binding and not subject to further review unless reopened and vacated by the MAC. The MAC's dismissal of a request for hearing is also binding and not subject to judicial review.

§ 405.1118 Obtaining evidence from the MAC.

A party may request and receive a copy of all or part of the record of the ALJ hearing, including the exhibits list, documentary evidence, and a copy of the tape of the oral proceedings. However, the party may be asked to pay the costs of providing these items. If a party requests evidence from the MAC and an opportunity to comment on that evidence, the time beginning with the MAC's receipt of the request for evidence through the expiration of the time granted for the party's response will not be counted toward the 90-day adjudication deadline.

§ 405.1120 Filing briefs with the MAC.

Upon request, the MAC will give the party requesting review, as well as all other parties, a reasonable opportunity to file briefs or other written statements about the facts and law relevant to the case. Any party who submits a brief or statement must send a copy to all of the other parties. Unless the party requesting review files the brief or other statement with the request for review, the time beginning with the date of receipt of the request to submit the brief and ending with the date the brief is received by the MAC will not be counted toward the adjudication timeframe set forth in § 405.1100. The MAC may also request, but not require, CMS or its contractor to file a brief or position paper if the MAC determines that it is necessary to resolve the issues in the case. The MAC will not draw any

adverse inference if CMS or a contractor either participates, or decides not to participate in MAC review.

§405.1122 What evidence may be submitted to the MAC.

(a) *Appeal before the MAC on request for review of ALJ's decision.* (1) If the MAC is reviewing an ALJ's decision, the MAC limits its review of the evidence to the evidence contained in the record of the proceedings before the ALJ. However, if the hearing decision decides a new issue that the parties were not afforded an opportunity to address at the ALJ level, the MAC considers any evidence related to that issue that is submitted with the request for review.

(2) If the MAC determines that additional evidence is needed to resolve the issues in the case and the hearing record indicates that the previous decision-makers have not attempted to obtain the evidence, the MAC may remand the case to an ALJ to obtain the evidence and issue a new decision.

(b) *Appeal before MAC as a result of appellant's request for escalation.* (1) If the MAC is reviewing a case that is escalated from the ALJ level to the MAC, the MAC will decide the case based on the record constructed at the QIC and any additional evidence, including oral testimony, entered in the record by the ALJ before the case was escalated.

(2) If the MAC receives additional evidence with the request for escalation that is material to the question to be decided, or determines that additional evidence is needed to resolve the issues in the case, and the record provided to the MAC indicates that the previous decision-makers did not attempt to obtain the evidence before escalation, the MAC may remand the case to an ALJ to consider or obtain the evidence and issue a new decision.

(c) *Evidence related to issues previously considered by the QIC.* (1) If new evidence related to issues previously considered by the QIC is submitted to the MAC by a provider, supplier, or a beneficiary represented by a provider or supplier, the MAC must determine if the provider, supplier, or the beneficiary represented by a provider or supplier had good cause for submitting it for the first time at the MAC level.

(2) If the MAC determines that good cause does not exist, the MAC must exclude the evidence from the proceeding, may not consider it in reaching a decision, and may not remand the issue to an ALJ.

(3) The MAC must notify all parties if it excludes the evidence. The MAC may remand to an ALJ if—

(i) The ALJ did not consider the new evidence submitted by the provider, supplier, or beneficiary represented by a provider or supplier because good cause did not exist; and

(ii) The MAC finds that good cause existed under §405.1028 and the ALJ should have reviewed the evidence.

(iii) The new evidence is submitted by a party that is not a provider, supplier, or a beneficiary represented by a provider or supplier.

(d) *Subpoenas.* (1) When it is reasonably necessary for the full presentation of a case, the MAC may, on its own initiative or at the request of a party, issue subpoenas requiring a party to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying.

(2) A party's request for a subpoena must—

(i) Give a sufficient description of the documents to be produced;

(ii) State the important facts that the documents are expected to prove; and

(iii) Indicate why these facts could not be proven without issuing a subpoena.

(3) A party to the MAC review on escalation that wishes to subpoena documents must file a written request that complies with the requirements set out in paragraph (d)(2) of this section within 10 calendar days of the request for escalation.

(4) A subpoena will issue only where a party—

(i) Has sought discovery;

(ii) Has filed a motion to compel;

(iii) Has had that motion granted; and

(iv) Nevertheless, has still not received the requested discovery.

(e) Reviewability of subpoena rulings—

(1) *General rule.* A MAC ruling on a subpoena request is not subject to immediate review by the Secretary.

(2) Exception. (i) To the extent a subpoena compels disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the MAC, the Secretary may review immediately that subpoena or portion of the subpoena.

(ii) Upon notice to the MAC that a party or non-party, as applicable, intends to seek Secretary review of the subpoena, the MAC must stay all proceedings affected by the subpoena.

(iii) The MAC determines the length of the stay under the circumstances of a given case, but in no event is less than 15 days after the day on which the MAC received notice of the party or non-party's intent to seek Secretary review.

(iv) If the Secretary grants a request for review, the subpoena or portion of the subpoena, as applicable, is stayed until the Secretary issues a written decision that affirms, reverses, modifies, or remands the MAC's action for the subpoena.

(v) If the Secretary does not grant review or take own motion review within the time allotted for the stay, the stay is lifed and the MAC's action stands.

(f) *Enforcement.* (1) If the MAC determines, whether on its own motion or at the request of a party, that a party or non-party subject to a subpoena issued under this section has refused to comply with the subpoena, the MAC may request the Secretary to seek enforcement of the subpoena in accordance with section 205(c) of the Act, 42 U.S.C. 405(c).

(2) Any enforcement request by the MAC must consist of a written notice to the Secretary describing in detail the MAC's findings of noncompliance and its specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the party or nonparty subject to the subpoena.

(3) The MAC must promptly mail a copy of the notice and related documents to the party or non-party subject to the subpoena, and to any other party and affected non-party to the appeal.

(4) If the Secretary does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the subpoena stands.

§ 405.1124 Oral argument.

A party may request to appear before the MAC to present oral argument.

(a) The MAC grants a request for oral argument if it decides that the case raises an important question of law, policy, or fact that cannot be readily decided based on written submissions alone.

(b) The MAC may decide on its own that oral argument is necessary to decide the issues in the case. If the MAC decides to hear oral argument, it tells the parties of the time and place of the oral argument at least 10 days before the scheduled date.

(c) In case of a previously unrepresented beneficiary, a newly hired representative may request an extension of time for preparation of the oral argument and the MAC must consider whether the extension is reasonable.

(d) The MAC may also request, but not require, CMS or its contractor to appear before it if the MAC determines that it may be helpful in resolving the issues in the case.

(e) The MAC will not draw any inference if CMS or a contractor decides not to participate in the oral argument.

§ 405.1126 Case remanded by the MAC.

(a) *When the MAC may remand a case.* Except as specified in § 405.1122(c), the MAC may remand a case in which additional evidence is needed or additional action by the ALJ is required. The MAC will designate in its remand order whether the ALJ will issue a final decision or a recommended decision on remand.

(b) *Action by ALJ on remand.* The ALJ will take any action that is ordered by the MAC and may take any additional action that is not inconsistent with the MAC's remand order.

(c) *Notice when case is returned with a recommended decision.* When the ALJ sends a case to the MAC with a recommended decision, a notice is mailed to the parties at their last known address. The notice tells them that the

case was sent to the MAC, explains the rules for filing briefs or other written statements with the MAC, and includes a copy of the recommended decision.

(d) *Filing briefs with the MAC when ALJ issues recommended decision.* (1) Any party to the recommended decision may file with the MAC briefs or other written statements about the facts and law relevant to the case within 20 days of the date on the recommended decision. Any party may ask the MAC for additional time to file briefs or statements. The MAC will extend this period, as appropriate, if the party shows that it has good cause for requesting the extension.

(2) All other rules for filing briefs with and obtaining evidence from the MAC follow the procedures explained in this subpart.

(e) *Procedures before the MAC.* (1) The MAC, after receiving a recommended decision, will conduct proceedings and issue its decision or dismissal according to the procedures explained in this subpart.

(2) If the MAC determines that more evidence is required, it may again remand the case to an ALJ for further inquiry into the issues, rehearing, receipt of evidence, and another decision or recommended decision. However, if the MAC decides that it can get the additional evidence more quickly, it will take appropriate action.

§405.1128 Action of the MAC.

(a) After it has reviewed all the evidence in the administrative record and any additional evidence received, subject to the limitations on MAC consideration of additional evidence in §405.1122, the MAC will make a decision or remand the case to an ALJ.

(b) The MAC may adopt, modify, or reverse the ALJ hearing decision or recommended decision.

(c) The MAC mails a copy of its decision to all the parties at their last known addresses. For overpayment cases involving multiple beneficiaries where there is no beneficiary liability the MAC may choose to send written notice only to the appellant. In the event the decision will result in a payment to a provider or supplier, the Medicare contractor must issue any electronic or paper remittance advice notice to that provider or supplier.

§405.1130 Effect of the MAC's decision.

The MAC's decision is binding on all parties unless a Federal district court issues a decision modifying the MAC's decision or the decision is revised as the result of a reopening in accordance with §405.980. A party may file an action in a Federal district court within 60 days after the date it receives notice of the MAC's decision.

§405.1132 Request for escalation to Federal court.

(a) If the MAC does not issue a decision or dismissal or remand the case to an ALJ within the adjudication period specified in §405.1100, or as extended as provided in this subpart, the appellant may request that the appeal, other than an appeal of an ALJ dismissal, be escalated to Federal district court. Upon receipt of a request for escalation, the MAC may—

(1) Issue a decision or dismissal or remand the case to an ALJ, if that action is issued within the latter of 5 calendar days of receipt of the request for escalation or 5 calendar days from the end of the applicable adjudication time period set forth in §405.1100; or

(2) If the MAC is not able to issue a decision or dismissal or remand as set forth in paragraph (a)(1) of this section, it will send a notice to the appellant acknowledging receipt of the request for escalation and confirming that it is not able to issue a decision, dismissal or remand order within the statutory time frame.

(b) A party may file an action in a Federal district court within 60 days after the date it receives the MAC's notice that the MAC is not able to issue a final action or remand unless the party is appealing an ALJ dismissal.

§405.1134 Extension of time to file action in Federal district court.

(a) Any party to the MAC's decision or to a request for EAJR that has been certified by the review entity other than CMS may request that the time for filing an action in a Federal district court be extended.

(b) The request must—

(1) Be in writing.

(2) Give the reasons why the action was not filed within the stated time period.

(3) Be filed with the MAC.

(c) If the party shows that he or she had good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the MAC uses the standards specified in § 405.942(b)(2) or (b)(3).

§ 405.1136 Judicial review.

(a) *General rules.* (1) To the extent authorized by sections 1869, 1876(c)(5)(B), and 1879(d) of the Act, a party to a MAC decision, or an appellant who requests escalation to Federal district court if the MAC does not complete its review of the ALJ's decision within the applicable adjudication period, may obtain a court review if the amount remaining in controversy satisfies the requirements of § 405.1006(c).

(2) If the MAC's adjudication period set forth in § 405.1100 expires and the appellant does not request escalation to Federal district court, the case remains with the MAC until a final action is issued.

(b) *Court in which to file civil action.* (1) Any civil action described in paragraph (a) of this section must be filed in the district court of the United States for the judicial district in which the party resides or where such individual, institution, or agency has its principal place of business.

(2) If the party does not reside within any judicial district, or if the individual, institution, or agency does not have its principal place of business within any such judicial district, the civil action must be filed in the District Court of the United States for the District of Columbia.

(c) *Time for filing civil action.* (1) Any civil action described in paragraph (a) of this section must be filed within the time periods specified in § 405.1130, § 405.1132, or § 405.1134, as applicable.

(2) For purposes of this section, the date of receipt of the notice of the MAC's decision or the MAC's notice that it is not able to issue a decision within the statutory timeframe shall be presumed to be 5 calendar days after the date of the notice, unless there is a reasonable showing to the contrary.

(3) Where a case is certified for judicial review in accordance with the expedited access to judicial review process in § 405.990, the civil action must be filed within 60 days after receipt of the review entity's certification, except where the time is extended by the ALJ or MAC, as applicable, upon a showing of good cause.

(d) *Proper defendant.* (1) In any civil action described in paragraph (a) of this section, the Secretary of HHS, in his or her official capacity, is the proper defendant. Any civil action properly filed shall survive notwithstanding any change of the person holding the Office of the Secretary of HHS or any vacancy in such office.

(2) If the complaint is erroneously filed against the United States or against any agency, officer, or employee of the United States other than the Secretary, the plaintiff will be notified that he or she has named an incorrect defendant and is granted 60 days from the date of receipt of the notice in which to commence the action against the correct defendant, the Secretary.

(e) *Prohibition against judicial review of certain Part B regulations or instructions.* Under section 1869(e)(1) of the Act, a court may not review a regulation or instruction that relates to a method of payment under Medicare Part B if the regulation was published, or the instructions issued, before January 1, 1991.

(f) *Standard of review.* (1) Under section 205(g) of the Act, the findings of the Secretary of HHS as to any fact, if supported by substantial evidence, are conclusive.

(2) When the Secretary's decision is adverse to a party due to a party's failure to submit proof in conformity with a regulation prescribed under section 205(a) of the Act pertaining to the type of proof a party must offer to establish entitlement to payment, the court will review only whether the proof conforms with the regulation and the validity of the regulation.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37705, June 30, 2005]

§405.1138 Case remanded by a Federal district court.

When a Federal district court remands a case to the Secretary for further consideration, unless the court order specifies otherwise, the MAC, acting on behalf of the Secretary, may make a decision, or it may remand the case to an ALJ with instructions to take action and either issue a decision, take other action, or return the case to the MAC with a recommended decision. If the MAC remands a case, the procedures specified in §405.1140 will be followed.

§405.1140 MAC review of ALJ decision in a case remanded by a Federal district court.

(a) *General rules.* (1) In accordance with §405.1138, when a case is remanded by a Federal district court for further consideration and the MAC remands the case to an ALJ, a decision subsequently issued by the ALJ becomes the final decision of the Secretary unless the MAC assumes jurisdiction.

(2) The MAC may assume jurisdiction based on written exceptions to the decision of the ALJ that a party files with the MAC or based on its authority under paragraph (c) of this section.

(3) The MAC either makes a new, independent decision based on the entire record that will be the final decision of the Secretary after remand, or remands the case to an ALJ for further proceedings.

(b) *A party files exceptions disagreeing with the decision of the ALJ.* (1) If a party disagrees with an ALJ decision described in paragraph (a) of this section, in whole or in part, he or she may file exceptions to the decision with the MAC. Exceptions may be filed by submitting a written statement to the MAC setting forth the reasons for disagreeing with the decision of the ALJ. The party must file exceptions within 30 days of the date the party receives the decision of the ALJ or submit a written request for an extension within the 30-day period. The MAC will grant a timely request for a 30-day extension. A request for an extension of more than 30 days must include a statement of reasons as to why the party needs the additional time and may be granted if the MAC finds good cause under the standard established in §405.942(b)(2) or (b)(3).

(2) If written exceptions are timely filed, the MAC considers the party's reasons for disagreeing with the decision of the ALJ. If the MAC concludes that there is no reason to change the decision of the ALJ, it will issue a notice addressing the exceptions and explaining why no change in the decision of the ALJ is warranted. In this instance, the decision of the ALJ is the final decision of the Secretary after remand.

(3) When a party files written exceptions to the decision of the ALJ, the MAC may assume jurisdiction at any time. If the MAC assumes jurisdiction, it makes a new, independent decision based on its consideration of the entire record adopting, modifying, or reversing the decision of the ALJ or remanding the case to an ALJ for further proceedings, including a new decision. The new decision of the MAC is the final decision of the Secretary after remand.

(c) *MAC assumes jurisdiction without exceptions being filed.* (1) Any time within 60 days after the date of the decision of the ALJ, the MAC may decide to assume jurisdiction of the case even though no written exceptions have been filed.

(2) Notice of this action is mailed to all parties at their last known address.

(3) The parties will be provided with the opportunity to file briefs or other written statements with the MAC about the facts and law relevant to the case.

(4) After the briefs or other written statements are received or the time allowed (usually 30 days) for submitting them has expired, the MAC will either issue a final decision of the Secretary affirming, modifying, or reversing the decision of the ALJ, or remand the case to an ALJ for further proceedings, including a new decision.

(d) *Exceptions are not filed and the MAC does not otherwise assume jurisdiction.* If no exceptions are filed and the MAC does not assume jurisdiction of the cases within 60 days after the date of the ALJ's decision, the decision of the ALJ becomes the final decision of the Secretary after remand.

Subpart J—Expedited Determinations and Reconsiderations of Provider Service Terminations, and Procedures for Inpatient Hospital Discharges

SOURCE: 69 FR 69624, Nov. 26, 2004, unless otherwise noted.

§ 405.1200 Notifying beneficiaries of provider service terminations.

(a) *Applicability and scope.* (1) For purposes of §§ 405.1200 through 405.1204, the term, provider, is defined as a home health agency (HHA), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), or hospice.

(2) For purposes of §§ 405.1200 through 405.1204, a termination of Medicare-covered service is a discharge of a beneficiary from a residential provider of services, or a complete cessation of coverage at the end of a course of treatment prescribed in a discrete increment, regardless of whether the beneficiary agrees that the services should end. A termination does not include a reduction in services. A termination also does not include the termination of one type of service by the provider if the beneficiary continues to receive other Medicare-covered services from the provider.

(b) *Advance written notice of service terminations.* Before any termination of services, the provider of the service must deliver valid written notice to the beneficiary of the provider's decision to terminate services. The provider must use a standardized notice, as specified by CMS, in accordance with the following procedures:

(1) *Timing of notice.* A provider must notify the beneficiary of the decision to terminate covered services no later than 2 days before the proposed end of the services. If the beneficiary's services are expected to be fewer than 2 days in duration, the provider must notify the beneficiary at the time of admission to the provider. If, in a nonresidential setting, the span of time between services exceeds 2 days, the notice must be given no later than the next to last time services are furnished.

(2) *Content of the notice.* The standardized termination notice must include the following information:

(i) The date that coverage of services ends;

(ii) The date that the beneficiary's financial liability for continued services begins;

(iii) A description of the beneficiary's right to an expedited determination under § 405.1202, including information about how to request an expedited determination and about a beneficiary's right to submit evidence showing that services must continue;

(iv) A beneficiary's right to receive the detailed information specified under § 405.1202(f); and

(v) Any other information required by CMS.

(3) *When delivery of the notice is valid.* Delivery of the termination notice is valid if—

(i) The beneficiary (or the beneficiary's authorized representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents; and

(ii) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

(4) *If a beneficiary refuses to sign the notice.* The provider may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

(5) *Financial liability for failure to deliver valid notice.* A provider is financially liable for continued services until 2 days after the beneficiary receives valid notice as specified under paragraph (b)(3) of this section, or until the service termination date specified on the notice, whichever is later. A beneficiary may waive continuation of services if he or she agrees with being discharged sooner than the planned service termination date.

§ 405.1202 Expedited determination procedures.

(a) *Beneficiary's right to an expedited determination by the QIO.* A beneficiary has a right to an expedited determination by a QIO under the following circumstances:

(1) For services furnished by a nonresidential provider, the beneficiary disagrees with the provider of those services that services should be terminated, and a physician certifies that failure to continue the provision of the service(s) may place the beneficiary's health at significant risk.

(2) For services furnished by a residential provider or a hospice, the beneficiary disagrees with the provider's decision to discharge the beneficiary.

(b) *Requesting an expedited determination.* (1) A beneficiary who wishes to exercise the right to an expedited determination must submit a request for a determination to the QIO in the State in which the beneficiary is receiving those provider services, in writing or by telephone, by no later than noon of the calendar day following receipt of the provider's notice of termination. If the QIO is unable to accept the beneficiary's request, the beneficiary must submit the request by noon of the next day the QIO is available to accept a request.

(2) The beneficiary, or his or her representative, must be available to answer questions or to supply information that the QIO may request to conduct its review.

(3) The beneficiary may, but is not required to, submit evidence to be considered by a QIO in making its decision.

(4) If a beneficiary makes an untimely request for an expedited determination by a QIO, the QIO will accept the request and make a determination as soon as possible, but the 72-hour time frame under paragraph (e)(6) and the financial liability protection under paragraph (g) of this section do not apply.

(c) *Coverage of provider services.* Coverage of provider services continues until the date and time designated on the termination notice, unless the QIO reverses the provider's service termination decision. If the QIO's decision is delayed because the provider did not timely supply necessary information or records, the provider may be liable for the costs of any additional coverage, as determined by the QIO in accordance with paragraph (e)(7) of this section. If the QIO finds that the beneficiary did not receive valid notice, coverage of provider services continues until at least 2 days after valid notice has been received. Continuation of coverage is not required if the QIO determines that coverage could pose a threat to the beneficiary's health or safety.

(d) *Burden of proof.* When a beneficiary requests an expedited determination by a QIO, the burden of proof rests with the provider to demonstrate that termination of coverage is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies.

(1) In order for the QIO to determine whether the provider has met the burden of proof, the provider should supply any and all information that a QIO requires to sustain the provider's termination decision, consistent with paragraph (f) of this section.

(2) The beneficiary may submit evidence to be considered by a QIO in making its decision.

(e) *Procedures the QIO must follow.* (1) On the day the QIO receives the request for an expedited determination under paragraph (b) of this section, it must immediately notify the provider of those services that a request for an expedited determination has been made.

(2) The QIO determines whether the provider delivered valid notice of the termination decision consistent with §405.1200(b) and paragraph (f) of this section.

(3) The QIO examines the medical and other records that pertain to the services in dispute. If applicable, the QIO determines whether a physician has certified that failure to continue the provision of services may place the beneficiary's health at significant risk.

(4) The QIO must solicit the views of the beneficiary who requested the expedited determination.

(5) The QIO must provide an opportunity for the provider/practitioner to explain why the termination or discharge is appropriate.

(6) No later than 72 hours after receipt of the request for an expedited determination, the QIO must notify the beneficiary, beneficiary's physician, and the provider of services of its determination whether termination of

Medicare coverage is the correct decision, either on the basis of medical necessity or based on other Medicare coverage policies.

(7) If the QIO does not receive the information needed to sustain a provider's decision to terminate services, it may make its determination based on the evidence at hand, or it may defer a decision until it receives the necessary information. If this delay results in extended Medicare coverage of an individual's provider services, the provider may be held financially liable for these services, as determined by the QIO.

(8) The QIO's initial notification may be by telephone, followed by a written notice including the following information:

(i) The rationale for the determination;

(ii) An explanation of the Medicare payment consequences of the determination and the date a beneficiary becomes fully liable for the services; and

(iii) Information about the beneficiary's right to a reconsideration of the QIO's determination, including how to request a reconsideration and the time period for doing so.

(f) *Responsibilities of providers.* (1) When a QIO notifies a provider that a beneficiary has requested an expedited determination, the provider must send a detailed notice to the beneficiary by close of business of the day of the QIO's notification. The detailed termination notice must include the following information:

(i) A specific and detailed explanation why services are either no longer reasonable and necessary or are no longer covered;

(ii) A description of any applicable Medicare coverage rule, instruction, or other Medicare policy, including citations to the applicable Medicare policy rules or information about how the beneficiary may obtain a copy of the Medicare policy;

(iii) Facts specific to the beneficiary and relevant to the coverage determination that are sufficient to advise the beneficiary of the applicability of the coverage rule or policy to the beneficiary's case; and

(iv) Any other information required by CMS.

(2) Upon notification by the QIO of the request for an expedited determination, the provider must supply all information that the QIO needs to make its expedited determination, including a copy of the notices required under §405.1200(b) and under paragraph (f)(1) of this section. The provider must furnish this information as soon as possible, but no later than by close of business of the day the QIO notifies the provider of the request for an expedited determination. At the discretion of the QIO, the provider may make the information available by phone or in writing (with a written record of any information not transmitted initially in writing).

(3) At a beneficiary's request, the provider must furnish the beneficiary with a copy of, or access to, any documentation that it sends to the QIO including records of any information provided by telephone. The provider may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and/or delivering it to the beneficiary. The provider must accommodate such a request by no later than close of business of the first day after the material is requested.

(g) *Coverage during QIO review.* When a beneficiary requests an expedited determination in accordance with the procedures required by this section, the provider may not bill the beneficiary for any disputed services until the expedited determination process (and reconsideration process, if applicable) has been completed.

§ 405.1204 Expedited reconsiderations.

(a) *Beneficiary's right to an expedited reconsideration.* A beneficiary who is dissatisfied with a QIO's expedited determination may request an expedited reconsideration by the appropriate QIC.

(b) *Requesting an expedited reconsideration.* (1) A beneficiary who wishes to obtain an expedited reconsideration must submit a request for the reconsideration to the appropriate QIC, in writing or by telephone, by no later than noon of the calendar day following initial notification (whether by telephone

or in writing) receipt of the QIO's determination. If the QIC is unable to accept the beneficiary's request, the beneficiary must submit the request by noon of the next day the QIC is available to accept a request.

(2) The beneficiary, or his or her representative, must be available to answer questions or supply information that the QIC may request to conduct its reconsideration.

(3) The beneficiary may, but is not required to, submit evidence to be considered by a QIC in making its decision.

(4) A beneficiary who does not file a timely request for an expedited QIC reconsideration subsequently may request a reconsideration under the standard claims appeal process, but the coverage protections described in paragraph (f) of this section would not extend through this reconsideration, nor would the timeframes or the escalation process described in paragraphs (c)(3) and (c)(5) of this section, respectively.

(c) *Procedures the QIC must follow.* (1) On the day the QIC receives the request for an expedited determination under paragraph (b) of this section, the QIC must immediately notify the QIO that made the expedited determination and the provider of services of the request for an expedited reconsideration.

(2) The QIC must offer the beneficiary and the provider an opportunity to provide further information.

(3) Unless the beneficiary requests an extension in accordance with paragraph (c)(6) of this section, no later than 72 hours after receipt of the request for an expedited reconsideration, and any medical or other records needed for such reconsideration, the QIC must notify the QIO, the beneficiary, the beneficiary's physician, and the provider of services, of its decision on the reconsideration request.

(4) The QIC's initial notification may be done by telephone, followed by a written notice including:

(i) The rationale for the reconsideration decision;

(ii) An explanation of the Medicare payment consequences of the determination and the beneficiary's date of liability; and

(iii) Information about the beneficiary's right to appeal the QIC's reconsideration decision to an ALJ, including how to request an appeal and the time period for doing so.

(5) Unless the beneficiary requests an extension in accordance with paragraph (c)(6) of this section, if the QIC does not issue a decision within 72 hours of receipt of the request, the QIC must notify the beneficiary of his or her right to have the case escalated to the ALJ hearing level if the amount remaining in controversy after the QIO determination is $100 or more.

(6) A beneficiary requesting an expedited reconsideration under this section may request (either in writing or orally) that the QIC grant such additional time as the beneficiary specifies (not to exceed 14 days) for the reconsideration. If an extension is granted, the deadlines in paragraph (c)(3) of this section do not apply.

(d) *Responsibilities of the QIO.* (1) When a QIC notifies a QIO that a beneficiary has requested an expedited reconsideration, the QIO must supply all information that the QIC needs to make its expedited reconsideration as soon as possible, but no later than by close of business of the day that the QIC notifies the QIO of the request for an expedited reconsideration.

(2) At a beneficiary's request, the QIO must furnish the beneficiary with a copy of, or access to, any documentation that it sends to the QIC. The QIO may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and/or delivering it to the beneficiary. The QIO must accommodate the request by no later than close of business of the first day after the material is requested.

(e) *Responsibilities of the provider.* A provider may, but is not required to, submit evidence to be considered by a QIC in making its decision. If a provider fails to comply with a QIC's request for additional information beyond that furnished to the QIO for purposes of the expedited determination, the QIC makes its reconsideration decision based on the information available.

(f) *Coverage during QIC reconsideration process.* When a beneficiary requests an expedited reconsideration in accordance with the deadline specified in (b)(1) of this section, the provider may

not bill the beneficiary for any disputed services until the QIC makes its determination.

§ 405.1205 Notifying beneficiaries of hospital discharge appeal rights.

(a) *Applicability and scope.* (1) For purposes of § 405.1204, § 405.1205, § 405.1206, and § 405.1208, the term ''hospital'' is defined as any facility providing care at the inpatient hospital level, whether that care is short term or long term, acute or non acute, paid through a prospective payment system or other reimbursement basis, limited to specialty care or providing a broader spectrum of services. This definition includes critical access hospitals.

(2) For purposes of § 405.1204, § 405.1205, § 405.1206, and § 405.1208, a discharge is a formal release of a beneficiary from an inpatient hospital.

(b) *Advance written notice of hospital discharge rights.* For all Medicare beneficiaries, hospitals must deliver valid, written notice of a beneficiary's rights as a hospital inpatient, including discharge appeal rights. The hospital must use a standardized notice, as specified by CMS, in accordance with the following procedures:

(1) *Timing of notice.* The hospital must provide the notice at or near admission, but no later than 2 calendar days following the beneficiary's admission to the hospital.

(2) *Content of the notice.* The notice must include the following information:

(i) The beneficiary's rights as a hospital inpatient including the right to benefits for inpatient services and for post-hospital services in accordance with 1866(a)(1)(M) of the Act.

(ii) The beneficiary's right to request an expedited determination of the discharge decision including a description of the process under § 405.1206, and the availability of other appeals processes if the beneficiary fails to meet the deadline for an expedited determination.

(iii) The circumstances under which a beneficiary will or will not be liable for charges for continued stay in the hospital in accordance with 1866(a)(1)(M) of the Act.

(iv) A beneficiary's right to receive additional detailed information in accordance with § 405.1206(e).

(v) Any other information required by CMS.

(3) *When delivery of the notice is valid.* Delivery of the written notice of rights described in this section is valid if—

(i) The beneficiary (or the beneficiary's representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents, except as provided in paragraph (b)(4) of this section; and

(ii) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

(4) *If a beneficiary refuses to sign the notice.* The hospital may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

(c) *Follow up notification.* (1) The hospital must present a copy of the signed notice described in paragraph (b)(2) of this section to the beneficiary (or beneficiary's representative) prior to discharge. The notice should be given as far in advance of discharge as possible, but not more than 2 calendar days before discharge.

(2) Follow up notification is not required if the notice required under § 405.1205(b) is delivered within 2 calendar days of discharge.

[71 FR 68720, Nov. 27, 2006]

§ 405.1206 Expedited determination procedures for inpatient hospital care.

(a) *Beneficiary's right to an expedited determination by the QIO.* A beneficiary has a right to request an expedited determination by the QIO when a hospital (acting directly or through its utilization review committee), with physician concurrence, determines that inpatient care is no longer necessary.

(b) *Requesting an expedited determination.* (1) A beneficiary who wishes to exercise the right to an expedited determination must submit a request to the QIO that has an agreement with the hospital as specified in § 476.78 of this chapter. The request must be made no

later than the day of discharge and may be in writing or by telephone.

(2) The beneficiary, or his or her representative, upon request by the QIO, must be available to discuss the case.

(3) The beneficiary may, but is not required to, submit written evidence to be considered by a QIO in making its decision.

(4) A beneficiary who makes a timely request for an expedited QIO review in accordance with paragraph (b)(1) of this section is subject to the financial liability protections under paragraphs (f)(1) and (f)(2) of this section, as applicable.

(5) A beneficiary who fails to make a timely request for an expedited determination by a QIO, as described in paragraph (b)(1) of this section, and remains in the hospital without coverage, still may request an expedited QIO determination at any time during the hospitalization. The QIO will issue a decision in accordance with paragraph (d)(6)(ii) of this section, however, the financial liability protection under paragraphs (f)(1) and (f)(2) of this section does not apply.

(6) A beneficiary who fails to make a timely request for an expedited determination in accordance with paragraph (b)(1) of this section, and who is no longer an inpatient in the hospital, may request QIO review within 30 calendar days after the date of discharge, or at any time for good cause. The QIO will issue a decision in accordance with paragraph (d)(6)(iii) of this section; however, the financial liability protection under paragraphs (f)(1) and (f)(2) of this section does not apply.

(c) *Burden of proof.* When a beneficiary (or his or her representative, if applicable) requests an expedited determination by a QIO, the burden of proof rests with the hospital to demonstrate that discharge is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies. Consistent with paragraph (e)(2) of this section, the hospital should supply any and all information that a QIO requires to sustain the hospital's discharge determination.

(d) *Procedures the QIO must follow.* (1) When the QIO receives the request for an expedited determination under paragraph (b)(1) of this section, it must immediately notify the hospital that a request for an expedited determination has been made.

(2) The QIO determines whether the hospital delivered valid notice consistent with §405.1205(b)(3).

(3) The QIO examines the medical and other records that pertain to the services in dispute.

(4) The QIO must solicit the views of the beneficiary (or the beneficiary's representative) who requested the expedited determination.

(5) The QIO must provide an opportunity for the hospital to explain why the discharge is appropriate.

(6)(i) When the beneficiary requests an expedited determination in accordance with paragraph (b)(1) of this section, the QIO must make a determination and notify the beneficiary, the hospital, and physician of its determination within one calendar day after it receives all requested pertinent information.

(ii) When the beneficiary makes an untimely request for an expedited determination, and remains in the hospital, consistent with paragraph (b)(5) of this section, the QIO will make a determination and notify the beneficiary, the hospital, and the physician of its determination within 2 calendar days following receipt of the request and pertinent information.

(iii) When the beneficiary makes an untimely request for an expedited determination, and is no longer an inpatient in the hospital, consistent with paragraph (b)(6) of this section, the QIO will make a determination and notify the beneficiary, the hospital, and physician of its determination within 30 calendar days after receipt of the request and pertinent information.

(7) If the QIO does not receive the information needed to sustain a hospital's decision to discharge, it may make its determination based on the evidence at hand, or it may defer a decision until it receives the necessary information. If this delay results in extended Medicare coverage of an individual's hospital services, the hospital may be held financially liable for these services, as determined by the QIO.

(8) When the QIO issues an expedited determination, the QIO must notify the beneficiary, the physician, and hospital

of its decision by telephone, followed by a written notice that must include the following information:

(i) The basis for the determination.

(ii) A detailed rationale for the determination.

(iii) An explanation of the Medicare payment consequences of the determination and the date a beneficiary becomes fully liable for the services.

(iv) Information about the beneficiary's right to a reconsideration of the QIO's determination as set forth in § 405.1204, including how to request a reconsideration and the time period for doing so.

(e) *Responsibilities of hospitals.* (1) When a QIO notifies a hospital that a beneficiary has requested an expedited determination, the hospital must deliver a detailed notice to the beneficiary as soon as possible but no later than noon of the day after the QIO's notification. The detailed notice must include the following information:

(i) A detailed explanation why services are either no longer reasonable and necessary or are otherwise no longer covered.

(ii) A description of any applicable Medicare coverage rule, instruction, or other Medicare policy, including information about how the beneficiary may obtain a copy of the Medicare policy.

(iii) Facts specific to the beneficiary and relevant to the coverage determination that are sufficient to advise the beneficiary of the applicability of the coverage rule or policy to the beneficiary's case.

(iv) Any other information required by CMS.

(2) Upon notification by the QIO of the request for an expedited determination, the hospital must supply all information that the QIO needs to make its expedited determination, including a copy of the notices required as specified in § 405.1205 (b) and (c) and paragraph (e)(1) of this section. The hospital must furnish this information as soon as possible, but no later than by noon of the day after the QIO notifies the hospital of the request for an expedited determination. At the discretion of the QIO, the hospital must make the information available by phone or in writing (with a written record of any information not transmitted initially in writing).

(3) At a beneficiary's (or representative's) request, the hospital must furnish the beneficiary with a copy of, or access to, any documentation that it sends to the QIO, including written records of any information provided by telephone. The hospital may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and/or delivering it to the beneficiary. The hospital must accommodate such a request by no later than close of business of the first day after the material is requested.

(f) *Coverage during QIO expedited review*—(1) *General rule and liability while QIO review is pending.* If the beneficiary remains in the hospital past midnight of the discharge date ordered by the physician, and the hospital, the physician who concurred with the discharge determination, or the QIO subsequently finds that the beneficiary requires inpatient hospital care, the beneficiary is not financially responsible for continued care (other than applicable coinsurance and deductible) until the hospital once again determines that the beneficiary no longer requires inpatient care, secures concurrence from the physician responsible for the beneficiary's care or the QIO, and notifies the beneficiary with a notice consistent with 405.1205 (c).

(2) *Timely filing and limitation on liability.* If a beneficiary files a request for an expedited determination by the QIO in accordance with paragraph (b)(1) of this section, the beneficiary is not financially responsible for inpatient hospital services (other than applicable coinsurance and deductible) furnished before noon of the calendar day after the date the beneficiary (or his or her representative) receives notification (either orally or in writing) of the expedited determination by the QIO.

(3) *Untimely request and liability.* When a beneficiary does not file a request for an expedited determination by the QIO in accordance with paragraph (b) of this section, but remains in the hospital past the discharge date, that beneficiary may be held responsible for

charges incurred after the date of discharge or as otherwise stated by the QIO.

(4) *Hospital requests an expedited review.* When the hospital requests a review in accordance with §405.1208, and the QIO concurs with the hospital's discharge determination, a hospital may not charge the beneficiary until the date specified by the QIO.

(g) *Effect of an expedited QIO determination.* The QIO determination is binding upon the beneficiary, physician, and hospital, except in the following circumstances:

(1) *Right to request a reconsideration.* If the beneficiary is still an inpatient in the hospital and is dissatisfied with the determination, he or she may request a reconsideration according to the procedures described in §405.1204.

(2) *Right to pursue the general claims appeal process.* If the beneficiary is no longer an inpatient in the hospital and is dissatisfied with this determination, the determination is subject to the general claims appeal process.

[71 FR 68721, Nov. 27, 2006]

§405.1208 Hospital requests expedited QIO review.

(a) *General rule.* (1) If the hospital (acting directly or through its utilization review committee) believes that the beneficiary does not require further inpatient hospital care but is unable to obtain the agreement of the physician, it may request an expedited determination by the QIO.

(2) When the hospital requests review, and the QIO concurs with the hospital's discharge determination, a hospital may not charge a beneficiary until the date specified by the QIO in accordance with 405.1206(f)(4).

(b) *Procedures hospital must follow.* (1) The hospital must (acting directly or through its utilization review committee) notify the beneficiary (or his or her representative) that it has requested that review.

(2) The hospital must supply any pertinent information the QIO requires to conduct its review and must make it available by phone or in writing, by close of business of the first full working day immediately following the day the hospital submits the request for review.

(c) *Procedures the QIO must follow.* (1) The QIO must notify the hospital that it has received the request for review and must notify the hospital if it has not received all pertinent records.

(2) The QIO must examine the pertinent records pertaining to the services.

(3) The QIO must solicit the views of the beneficiary in question.

(4) The QIO must make a determination and notify the beneficiary, the hospital, and physician within 2 working days of the hospital's request and receipt of any pertinent information submitted by the hospital.

(d) *Notice of an expedited determination.* (1) When a QIO issues an expedited determination as stated in paragraph (c)(4) of this section, it must notify the beneficiary, physician, and hospital of its decision, by telephone and subsequently in writing.

(2) A written notice of the expedited initial determination must contain the following:

(i) The basis for the determination;.

(ii) A detailed rationale for the determination;

(iii) A statement explaining the Medicare payment consequences of the expedited determination and date of liability, if any; and

(iv) A statement informing the beneficiary of his or her appeal rights and the timeframe for requesting an appeal.

(e) *Effect of an expedited determination.* The expedited determination under this section is binding upon the beneficiary, physician, and hospital, except in the following circumstances:

(1) *When a beneficiary remains in the hospital.* If the beneficiary is still an inpatient in the hospital and is dissatisfied with this determination, he or she may request a reconsideration according to the procedures described in §405.1204. The procedures described in §405.1204 will apply to reconsiderations requested under this section. If the beneficiary does not make a request in accordance with §405.1204(b)(1), the timeframes described in §405.1204(c)(3), the escalation procedures described in §405.1204(c)(5), and the coverage rule described in §405.1204(f) will not apply.

(2) *When a beneficiary is no longer an inpatient in the hospital.* If the beneficiary is no longer an inpatient in the

hospital and is dissatisfied with this determination, this determination is subject to the general claims appeal process.

[69 FR 69624, Nov. 26, 2004, as amended at 71 FR 68722, Nov. 27, 2006]

Subparts K–Q [Reserved]

Subpart R—Provider Reimbursement Determinations and Appeals

AUTHORITY: Secs. 205, 1102, 1814(b), 1815(a), 1833, 1861(v), 1871, 1872, 1878, and 1886 of the Social Security Act (42 U.S.C. 405, 1302, 1395f(b), 1395g(a), 1395l, 1395x(v), 1395hh, 1395ii, 1395oo, and 1395ww).

SOURCE: 39 FR 34515, Sept. 26, 1974, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.1801 Introduction.

(a) *Definitions.* As used in this subpart:

Administrator means the Administrator or Deputy Administrator of CMS.

Administrator's review means that review provided for in section 1878(f) of the Act (42 U.S.C. 1395oo(f)) and § 405.1875.

Board means the Provider Reimbursement Review Board established in accordance with section 1878 of the Act (42 U.S.C. 1395oo) and § 405.1845.

Board hearing means that hearing provided for in section 1878(a) of the Act (42 U.S.C. 1395oo(a)), and § 405.1835.

Date of filing and *date of submission of materials* mean the day of the mailing (as evidenced by the postmark) or hand-delivery of materials, unless otherwise defined in this subpart.

Date of receipt means the date on the return receipt of ''return receipt requested'' mail, unless otherwise defined in this subpart.

Intermediary determination means the following:

(1) With respect to a provider of services that has filed a cost report under §§ 413.20 and 413.24(f) of this chapter, the term means a determination of the amount of total reimbursement due the provider, pursuant to § 405.1803 following the close of the provider's cost reporting period, for items and services furnished to beneficiaries for which reimbursement may be made on a reasonable cost basis under Medicare for the period covered by the cost report.

(2) With respect to a hospital that receives payments for inpatient hospital services under the prospective payment system (part 412 of this chapter), the term means a determination of the total amount of payment due the hospital, pursuant to § 405.1803 following the close of the hospital's cost reporting period, under that system for the period covered by the determination.

(3) For purposes of appeal to the Provider Reimbursement Review Board, the term is synonymous with the phrases ''intermediary's final determination'' and ''final determination of the Secretary'', as those phrases are used in section 1878(a) of the Act.

(4) For purposes of § 405.376 concerning claims collection activities, the term does not include an action by CMS with respect to a compromise of a Medicare overpayment claim, or termination or suspension of collection action on an overpayment claim, against a provider or physician or other supplier.

Intermediary hearing means that hearing provided for in § 405.1809.

(b) *General rule*—(1) *Providers.* The principles of reimbursement for determining reasonable cost and prospective payment are contained in parts 413 and 412, respectively, of this chapter. In order to be reimbursed for covered services furnished to Medicare beneficiaries, providers of services are obliged to file cost reports with their intermediaries as specified in § 413.24(f) of this chapter. Where the term ''provider'' appears in this subpart, it includes hospitals paid under the prospective payment system for purposes of applying the appeal procedures described in this subpart to those hospitals.

(2) *Other entities participating in Medicare Part A.* In addition to providers of services whose status as such is indicated in the Act, there are entities (such as health maintenance organizations) that do not meet the statutory test for providers of services, which may also participate in Medicare. These entities are required to file periodic cost reports and are reimbursed on

the basis of information furnished in the reports. Although the entities do not qualify for Board review, the rules as set forth in this subpart with respect to intermediary hearings are applicable to the entities to the maximum extent possible, for cost-reporting periods ending on or after December 31, 1971, where the amount of program reimbursement in controversy is at least $1,000.

(c) *Effective dates.* (1) Except as provided in paragraphs (c)(2) and (c)(3) of this section or in §405.1885(e), this subpart applies to all cost reporting periods ending on or after December 31, 1971, for which reimbursement may be made on a reasonable cost basis.

(2) Sections 405.1835 to 405.1877 apply only to cost reporting periods ending on or after June 30, 1973, for which reimbursement may be made on a reasonable cost basis.

(3) With respect to hospitals under the prospective payment system (see part 412 of this chapter), the appeals procedures in §§405.1811 to 405.1877 that apply become applicable with the hospital's first cost reporting period beginning on or after October 1, 1983.

[39 FR 34515, Sept. 26, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 48 FR 39834, Sept. 1, 1983; 48 FR 45773, Oct. 7, 1983; 49 FR 322, Jan. 3, 1984; 49 FR 23013, June 1, 1984; 51 FR 34793, Sept. 30, 1986; 61 FR 63749, Dec. 2, 1996]

§405.1803 Intermediary determination and notice of amount of program reimbursement.

(a) *General requirement.* Upon receipt of a provider's cost report, or amended cost report where permitted or required, the intermediary must within a reasonable period of time (see §405.1835(b)), furnish the provider and other parties as appropriate (see §405.1805) a written notice reflecting the intermediary's determination of the total amount of reimbursement due the provider. The intermediary must include the following information in the notice, as appropriate:

(1) *Reasonable cost.* The notice must—

(i) Explain the intermediary's determination of total program reimbursement due the provider on the basis of reasonable cost for the reporting period covered by the cost report or amended cost report; and

(ii) Relate this determination to the provider's claimed total program reimbursement due the provider for this period.

(2) *Prospective payment.* With respect to a hospital that receives payments for inpatient hospital services under the prospective payment system (see part 412 of this chapter), the intermediary must include in the notice its determination of the total amount of the payments due the hospital under that system for the cost reporting period covered by the notice. The notice must explain (with appropriate use of the applicable money amounts) any difference in the amount determined to be due, and the amounts received by the hospital during the cost reporting period covered by the notice.

(b) *Requirements for intermediary notices.* The intermediary must include in each notice appropriate references to law, regulations, CMS Rulings, or program instructions to explain why the intermediary's determination of the amount of program reimbursement for the period differs from the amount the provider claimed. The notice must also inform the provider of its right to an intermediary or Board hearing (see §§405.1809, 405.1811, 405.1815, 405.1835, and 405.1843) and that the provider must request the hearing within 180 days after the date of the notice.

(c) *Use of notice as basis for recoupment of overpayments.* The intermediary's determination contained in its notice is the basis for making the retroactive adjustment (required by §413.64(f) of this chapter) to any program payments made to the provider during the period to which the determination applies, including recoupment under §405.373 from ongoing payments to the provider of any overpayments to the provider identified in the determination. Recoupment is made notwithstanding any request for hearing on the determination the provider may make under §405.1811 or §405.1835.

[48 FR 39834, Sept. 1, 1983, as amended at 49 FR 322, Jan 3, 1984; 51 FR 34793, Sept. 30, 1986; 61 FR 63748, Dec. 2, 1996]

§ 405.1804 Matters not subject to administrative and judicial review under prospective payment.

Neither administrative nor judicial review is available for controversies about the following matters:

(a) The determination of the requirement, or the proportional amount, of any budget neutrality adjustment in the prospective payment rates.

(b) The establishment of—

(1) Diagnosis related groups (DRGs);

(2) The methodology for the classification of inpatient discharges within the DRGs; or

(3) Appropriate weighting factors that reflect the relative hospital resources used with respect to discharge within each DRG.

[49 FR 322, Jan. 1, 1984]

§ 405.1805 Parties to intermediary determination.

The parties to the intermediary's determination are the provider and any other entity found by the intermediary to be a related organization of the provider under § 413.17 of this chapter.

[48 FR 39835, Sept. 1, 1983, as amended at 51 FR 34793, Sept. 30, 1986]

§ 405.1807 Effect of intermediary determination.

The determination shall be final and binding on the party or parties to such determination unless:

(a) An intermediary hearing is requested in accordance with § 405.1811 and an intermediary hearing decision rendered in accordance with § 405.1831; or

(b) The intermediary determination is revised in accordance with § 405.1885; or

(c) A Board hearing is requested in accordance with § 405.1835 and a hearing decision rendered pursuant thereto.

§ 405.1809 Intermediary hearing procedures.

(a) *Hearings.* Each intermediary must establish and maintain written procedures for intermediary hearings, in accordance with the regulations in this subpart, for resolving issues that may arise between the intermediary and a provider concerning the amount of reasonable cost reimbursement, or prospective payment due the provider (except as provided in § 405.1804) under the Medicare program. The procedures must provide for a hearing on the intermediary determination contained in the notice of program reimbursement (§ 405.1803), if the provider files a timely request for a hearing.

(b) *Amount in controversy.* In order for an intermediary to grant a hearing, the following dates and amounts in controversy apply:

(1) For cost reporting periods ending prior to June 30, 1973, the amount of program reimbursement in controversy must be at least $1000.

(2) For cost reporting periods ending on or after June 30, 1973, the amount of program reimbursement in controversy must be at least $1000 but less than $10,000.

[48 FR 39835, Sept. 1, 1983, as amended at 49 FR 323, Jan. 1, 1984]

§ 405.1811 Right to intermediary hearing; time, place, form, and content of request for intermediary hearing.

(a) A provider that has been furnished a notice of amount of program reimbursement may request an intermediary hearing if it is dissatisfied with the intermediary's determination contained in the notice and the amount in controversy requirement described in § 405.1809 is met. The request must be in writing and be filed with the intermediary within 180 calendar days after the date of the notice. (See § 405.1835(c)). No other individual, entity, or party has the right to an intermediary hearing.

(b) The request must (1) identify the aspect(s) of the determination with which the provider is dissatisfied, and (2) explain why the provider believes the determination on these matters is incorrect, and (3) be submitted with any documentary evidence the provider considers necessary to support its position.

(c) Following the timely filing of the request for hearing, the provider may identify in writing, prior to the onset of the hearing proceedings, additional aspects of the determination with which it is dissatisfied and furnish any documentary evidence in support thereof. If such additional aspects are submitted, the hearing officer may

postpone the hearing to allow for his examination of such additional aspects.

[39 FR 34515, Sept. 26, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 48 FR 39835, Sept. 1, 1983]

§405.1813 Failure to timely request an intermediary hearing.

If a provider requests an intermediary hearing on an intermediary's determination after the time limit prescribed in §405.1811, the designated intermediary hearing officer or panel of hearing officers will dismiss the request and furnish the provider a written notice that explains the time limitation, except that for good cause shown, the time limit prescribed in §405.1811 may be extended. However, an extension may not be granted if the extension request is filed more than 3 years after the date of the original notice of the intermediary determination.

[48 FR 39835, Sept. 1, 1983]

§405.1815 Parties to the intermediary hearing.

The parties to the intermediary hearing shall be the parties to the intermediary determination and any other entity determined by the intermediary to be a related organization of such provider. Said parties shall be given reasonable notice of the time, date, and place of such hearing. Neither the intermediary nor the Centers for Medicare & Medicaid Services are parties (see §405.1819).

§405.1817 Hearing officer or panel of hearing officers authorized to conduct intermediary hearing; disqualification of officers.

The intermediary hearing provided for in §405.1809 shall be conducted by a hearing officer or panel of hearing officers designated by the intermediary. Such hearing officer or officers shall be persons knowledgeable in the field of health care reimbursement. The hearing officer or officers shall not have had any direct responsibility for the program reimbursement determination with respect to which a request for hearing is filed; no hearing officer (or officers) shall conduct a hearing in a case in which he is prejudiced or partial with respect to any party, or where he has any interest in the matter pending for determination before him. Notice of any objection which a party may have with respect to a hearing officer shall be presented in writing to such officer by the objecting party at the party's earliest opportunity. The hearing officer shall consider the objection and shall, at his discretion, either proceed in the conduct of the hearing or withdraw. If the hearing officer does not withdraw, the objecting party may, after the hearing, present his objections to an executive official of the intermediary, who shall rule promptly on the objection.

§405.1819 Conduct of intermediary hearing.

The hearing shall be open to all parties thereto (see §405.1815) and to representatives of the intermediary and of the Centers for Medicare & Medicaid Services (see §405.1815). The hearing officer(s) shall inquire fully into all of the matters at issue and shall receive into evidence the testimony and any documents which are relevant and material to such matters. If the hearing officer(s) believes that there is relevant and material evidence available which has not been presented at the hearing, he (they) may, at any time prior to the mailing of notice of the decision, reopen the hearing record for the receipt of such evidence. The order in which the evidence and the allegations shall be presented and the conduct of the hearing shall be at the discretion of the hearing officer(s).

§405.1821 Prehearing discovery and other proceedings prior to the intermediary hearing.

(a) Prehearing discovery shall be permitted upon timely request of any party. To be timely, a request for discovery and inspection shall be made before the beginning of the hearing. A reasonable time for inspection and reproduction of documents shall be provided by order of the hearing officer(s).

(b) If, in the discretion of the hearing officer(s), the purpose of defining the issues more clearly would be served, the hearing officer(s) may schedule a prehearing conference. For this purpose, a single member of a panel of hearing officers, when such is the case,

may be appointed to act for the panel with respect to prehearing activities.

§ 405.1823 Evidence at intermediary hearing.

Evidence may be received at the intermediary hearing even though inadmissible under the rules of evidence applicable to court procedure. The hearing officer(s) shall give the parties opportunity for submission and consideration of facts and arguments, and during the course of the hearing, should in ruling upon admissibility of evidence, exclude irrelevant, immaterial, or unduly repetitious evidence. The hearing officer(s) shall render a final ruling on the admissibility of evidence.

§ 405.1825 Witnesses at intermediary hearing.

The hearing officer(s) may examine the witnesses and shall allow the parties and their representatives to do so. Parties to the proceedings may also cross-examine witnesses.

§ 405.1827 Record of intermediary hearing.

A complete recordation of the proceedings at the intermediary hearing shall be made and transcribed in all cases. It shall be made available to any party upon request. The record will not be closed until a decision (see § 405.1831) has been issued.

§ 405.1829 Authority of hearing officer(s) at intermediary hearing.

(a) The hearing officer(s) in exercising his authority must comply with all the provisions of title XVIII of the Act and regulations issued thereunder, as well as with CMS Rulings issued under the authority of the Administrator of the Centers for Medicare & Medicaid Services (see 42 CFR 401.108), and with the general instructions issued by the Centers for Medicare & Medicaid Services in accordance with the Secretary's agreement with the intermediary.

(b) The determination of a fiscal intermediary that no payment may be made under title XVIII of the Act for any expense incurred for items and services furnished to an individual because such items and services are excluded from coverage pursuant to section 1862 of the Act, 42 U.S.C. 1395y (see subpart C of this part), shall not be reviewed by the hearing officer(s). Such determination shall be reviewed only in accordance with the applicable provisions of subparts G and H of this part.

§ 405.1831 Intermediary hearing decision and notice.

The hearing officer(s) shall, on a timely basis, render a decision in writing based on the evidence in the record; such decision shall constitute the final determination of the intermediary. In such decision, he will cite applicable law, regulations, CMS Rulings, and general instructions of the Centers for Medicare & Medicaid Services, as well as findings on all the matters in issue at the hearing. A copy of the decision will be mailed to all parties to the hearing at their last known addresses.

§ 405.1833 Effect of intermediary hearing decision.

The intermediary hearing decision provided for in § 405.1831 shall be final and binding upon all parties to the hearing unless such intermediary determination is revised in accordance with § 405.1885.

§ 405.1835 Right to Board hearing.

(a) *Criteria.* The provider (but no other individual, entity, or party) has a right to a hearing before the Board about any matter designated in § 405.1801(a)(1), if:

(1) An intermediary determination has been made with respect to the provider; and

(2) The provider has filed a written request for a hearing before the Board under the provisions described in § 405.1841(a)(1); and

(3) The amount in controversy (as determined in § 405.1839(a)) is $10,000 or more.

(b) *Prospective payment exceptions.* Except with respect to matters for which administrative or judicial review is not permitted as specified in § 405.1804, hospitals that are paid under the prospective payment system are entitled to hearings before the Board under this

section if they otherwise meet the criteria described in paragraph (a) of this section.

(c) *Right to hearing based on late intermediary determination about reasonable cost.* Notwithstanding the provisions of paragraph (a)(1) of this section, the provider also has a right to a hearing before the Board if an intermediary's determination concerning the amount of reasonable cost reimbursement due a provider is not rendered within 12 months after receipt by the intermediary of a provider's perfected cost report or amended cost report (as permitted or as required to furnish sufficient data for purposes of making such determination—see §405.1803(a)) provided such delay was not occasioned by the fault of the provider.

[48 FR 39835, Sept. 1, 1983]

§405.1837 Group appeal.

(a) *Criteria for group appeals.* Subject to paragraph (b) of this section, a group of providers may bring an appeal before the Board but only if—

(1) Each provider in the group is identified as one which would, upon the filing of a request for a hearing before the Board, but without regard to the $10,000 amount in controversy requirement, be entitled to a hearing under §405.1835;

(2) The matters at issue involve a common question of fact or of interpretation of law, regulations or CMS Rulings; and

(3) The amount in controversy is, in the aggregate, $50,000 or more.

(b) *Providers under common ownership or control.* Effective April 20, 1983, any appeal filed by providers that are under common ownership or control must be brought by the providers as a group appeal in accordance with the provisions of paragraph (a) of this section with respect to any matters involving an issue common to the providers and for which the amount in controversy is, in the aggregate, $50,000 or more (see §405.1841(a)(2)). A single provider involved in a group appeal that also wishes to appeal issues that are not common to the other providers in the group must file a separate hearing request (see §405.1841(a)(1)) and must separately meet the requirements in §405.1811 or §405.1835, as applicable.

[48 FR 39836, Sept. 1, 1983]

§405.1839 Amount in controversy.

(a) *Single appeals.* The $1,000 amount in controversy required under §405.1809 for an intermediary hearing and the $10,000 amount in controversy required under §405.1835 for a Board hearing is, as applicable to the matters for which the provider has requested a hearing, the combined total of the amounts computed as follows:

(1) *Providers under prospective payment.* For providers that are paid under the prospective payment system, by deducting—

(i) The total of the payment due the provider on other than a reasonable cost basis under the prospective payment system from the total amount that would be payable after a recomputation that takes into account any exclusion, exception, adjustment, or additional payment denied the provider under part 412 of this chapter, as applicable;

(ii) The total of the payment due the provider on a reasonable cost basis under the prospective payment system from the total reimbursable costs claimed by the provider; and

(iii) The adjusted total reimbursable costs due the provider on a reasonable cost basis under other than the prospective payment system from the total reimbursable costs claimed by the provider.

(2) *Providers not under prospective payment.* For providers that are not paid under the prospective payment system, by deducting the adjusted total reimbursable program costs due the provider on a reasonable cost basis from the total reimbursable costs claimed by the provider.

(b) *Group appeals.* The $50,000 amount in controversy required under §405.1837 for group appeals to the Board is, as applicable to the common matters for which the group of providers have requested a hearing, the combined total of the amounts computed as follows:

(1) *Providers under prospective payment.* For providers that are paid under the prospective payment system, by deducting—

(i) The total of the payment due the providers (in the aggregate) on other than a reasonable cost basis under the prospective payment system from the total amount that would be payable to the providers (in the aggregate) after a recomputation that takes into account any applicable exception, exclusion, adjustment, or additional payment denied the providers under part 412 of this chapter.

(ii) The total of the payment due the providers (in the aggregate) on a reasonable cost basis under the prospective payment system from the total reimbursable costs claimed in the aggregate by the providers; and

(iii) The adjusted total reimbursable costs due the providers (in the aggregate) on a reasonable cost basis under other than the prospective payment system from the total reimbursable costs claimed in the aggregate by the providers.

(2) *Providers not under prospective payment.* For providers that are not paid under the prospective payment system, by deducting the adjusted total reimbursable program costs due the providers (in the aggregate) on a reasonable cost basis from the total reimbursable costs claimed in the aggregate by the providers.

[49 FR 323, Jan. 3, 1984]

§ 405.1841 Time, place, form, and content of request for Board hearing.

(a) *General requirements.* (1) The request for a Board hearing must be filed in writing with the Board within 180 days of the date the notice of the intermediary's determination was mailed to the provider or, where notice of the determination was not timely rendered, within 180 days after the expiration of the period specified in § 405.1835(c). Such request for Board hearing must identify the aspects of the determination with which the provider is dissatisfied, explain why the provider believes the determination is incorrect in such particulars, and be accompanied by any documenting evidence the provider considers necessary to support its position. Prior to the commencement of the hearing proceedings, the provider may identify in writing additional aspects of the intermediary's determination with which it is dissatisfied and furnish any documentary evidence in support thereof.

(2) Effective April 20, 1983, any request for a Board hearing by providers that are under common ownership or control (see § 413.17 of this chapter) must be brought by the providers as a group appeal (see § 405.1837(b)) with respect to any matters at issue involving a question of fact or of interpretation of law, regulations, or CMS Rulings common to the providers and for which the amount in controversy is $50,000 or more in the aggregate. If a group appeal is filed, the provider seeking the appeal must be separately identified in the request for hearing, which must be prepared and filed consistently with the requirements of paragraph (a)(1) of this section.

(b) *Extension of time limit for good cause.* A request for a Board hearing filed after the time limit prescribed in paragraph (a) of this section shall be dismissed by the Board, except that for good cause shown, the time limit may be extended. However, no such extension shall be granted by the Board if such request is filed more than 3 years after the date the notice of the intermediary's determination is mailed to the provider.

[48 FR 39836, Sept. 1, 1983, as amended at 51 FR 34793, Sept. 30, 1986]

§ 405.1842 Expediting Board proceedings.

(a) *Basis and purpose.* This section implements section 1878(f)(1) of the Social Security Act, as amended by section 955 of Public Law 96–499 (42 U.S.C. 1395oo(f)(1)). The amendment provides an opportunity for providers to obtain expedited administrative review when the Board determines that it does not have the authority to decide a question of law, regulation, or CMS Ruling relevant to the case (see § 405.1867).

(b) *Basic rule.* (1) Except as provided in paragraph (b)(4) of this section, a provider may submit a written request to the Board, with supporting documentation, to determine whether the Board has the authority to decide a question of law, regulations, or CMS Rulings relevant to and controlling upon an issue to be reviewed by the Board. The Board is required to make

an expedited review determination in writing, either denying or granting the request, within 30 days after the date of receipt of the request, as defined in paragraph (1) of this section. The Board may also issue a determination on its own motion that it lacks authority to decide a question of law, regulations or CMS Rulings.

(2) The Board must determine that the provider (including each provider in a group appeal) is entitled to a hearing under section 1878(a) of the Act before making the determination described in paragraph (b)(1) of this section. Thus, the provider must file (or have already filed) a written request for a Board hearing that meets the requirements in §405.1841. The information and documentation required with respect to the filing of a request for a hearing is used by the Board to determine jurisdiction under section 1878(a) of the Act.

(3) A provider's request for an expedited review determination cannot be considered to be filed with the Board, nor can the 30-day time period during which the Board is required to make an expedited review determination begin, until such time as the Board accepts jurisdiction of the case.

(4) Proceedings conducted by the Board under an authority other than section 1878(a) of the Act and §§405.1835 through 405.1873 of this subpart are not hearings for purposes of this section and are not subject to the expedited Board proceedings set forth in this section. For example, proceedings concerning reimbursement for capital expenditures conducted under section 1122(f) of the Act and §405.1890 of this subpart are not hearings for purposes of this section. (Section 1122(f) specifically bars any administrative or judicial review.)

(c) *''Own motion'' review.* If the Board is considering issuing a determination on its own motion that it lacks the authority to decide a question of law, regulations, or CMS Rulings, it will notify the provider and intermediary of its proposed determination and allow them a reasonable period of time to file evidence or arguments either to support or oppose the proposed determination.

(d) *Provider requests.* (1) If a provider seeks an expedited Board proceeding, it must—(i) File its appropriately documented request in writing with the Board; and

(ii) Send a copy of the request and documentation simultaneously to the intermediary.

(2) The request to the Board for an expedited review determination must—(i) Identify the issues and the controlling law, regulation or CMS Ruling for which the Board is to make a determination;

(ii) Allege and demonstrate that there are no factual issues in dispute;

(iii) Contain an explanation of why the provider believes the Board cannot decide the legal issue or issues that are in dispute; and

(iv) Include all other information or details that support the request.

(3) If the information in the provider request is insufficient for the Board to determine whether it has the authority to decide an issue, the Board will request more information from the provider. Such a request will affect the 30-day time limit as provided in paragraph (i) of this section. If the provider does not send more information or sends inadequate information, the Board will determine that it has the authority to decide the issue and will begin the regular procedure for a hearing.

(e) *Intermediary participation.* (1) After receiving a copy of the provider's request for an expedited review determination, the intermediary may send comments to the Board on the provider's request and supporting documentation. The intermediary will send a copy of its comments to the provider simultaneously.

(2) If the intermediary's comments raise questions about the provider's request for expedited review, the Board may request additional information from the provider as provided in paragraph (d)(3) of this section.

(f) *Criteria for a Board determination.* The Board will review all documentation forwarded by the provider and the intermediary relevant to the request for a Board determination concerning the Board's authority to decide an issue. In its review, the Board will consider—

(1) The controlling facts in the case;

(2) The applicability of law, regulations, or CMS rulings;

(3) Whether there are factual issues for the Board to resolve; and

(4) Whether there are legal issues within the authority of the Board to decide.

(g) *Board determination.* (1) Within 30 days after the date of receipt (as defined in paragraph (i) of this section) of a provider's request and all necessary documentation the Board will issue a determination concerning its authority to decide the question of law, regulations, or CMS Rulings relevant to the issues identified by the provider in its request.

(2) If there are factual or legal issues in dispute on an issue within the authority of the Board to decide, the Board will not make an expedited review determination on the particular issue but will proceed with a hearing. The Board has the authority to decide when two or more issues are sufficiently related to preclude separation for purposes of an expedited review determination on one or more of them and a hearing on the other or others.

(3) The Board will promptly notify the provider in writing of its determination and will send a copy of the determination to the intermediary.

(4) The Board's determination concerning its authority or its lack of a determination is not subject to the Secretary's review under § 405.1875.

(h) *Effect of a Board decision.* (1) The Board's determination, issued on its own motion or at the request of a provider, that it lacks authority to decide a question of law, regulations or CMS Rulings is a final decision permitting a provider to seek judicial review with respect to the matter or matters in controversy contained in the determination, within 60 days of the date of the Board's determination.

(2) After the Board has determined that it does not have the authority to decide an issue, the provider will not be granted a hearing on the same issue.

(3) If the Board fails to issue an expedited review determination within 30 days of the date of receipt of a complete request (as determined under paragraph (i) of this section), the provider may, within 60 days from the end of that period, seek judicial review of the matters for which it requested the Board's determination.

(4) If the Board fails to make an expedited review determination within the required 30 days, it will begin regular hearing procedures as though it has the authority to decide the issue.

(5) If the provider seeks judicial review because the Board fails to make a determination as provided in paragraph (g)(1) of this section, it should notify the Board at the time it files for judicial review. The Board will not hold a hearing, even if one has been scheduled, on the matter or matters for which the provider is seeking judicial review.

(6) The Board's determination does not affect the right of the provider to a Board hearing for issues for which the provider did not request expedited review, or for which the Board determines it does have the authority to decide, or for which the Board did not make a determination and the provider did not request judicial review.

(i) *Date of receipt.* For purposes of this section, the date of receipt of the provider's request is the later of—

(1) The actual date of receipt by the Board of the information required under paragraph (d)(2) of this section, or of additional information requested by the Board under paragraph (d)(3) of this section, whichever the Board receives later; or

(2) The date indicated on the Board's written notification to the provider that the Board has accepted jurisdiction of the case.

(j) *Examples.* Below are examples showing when a provider may expect to receive an expedited review determination, in relation to various circumstances affecting its request for the determination.

(1) The provider requests a hearing and expedited review at or about the same time. If all information is complete, the Board could send notification that it has accepted jurisdiction of the case and the expedited review determination simultaneously.

(2) The provider requests both a hearing and an expedited review determination, and supplies complete information. The Board accepts jurisdiction

but, for example, because of the complexity of the case, the Board makes its expedited review determination within 30 days after it has accepted jurisdiction.

(3) The provider requests both a hearing and an expedited review determination, but the request for a hearing does not contain enough information for the Board to determine jurisdiction. The Board would request more information to determine jurisdiction and would make its expedited review determination within 30 days after it has accepted jurisdiction.

(4) The provider requests both a hearing and an expedited review determination, but does not send enough information for the Board to make an expedited review determination. Assuming the Board accepts jurisdiction, the Board would request more information about the request for expedited review and make its determination within 30 days after it receives the additional information.

(5) The provider requests an expedited review determination after the Board has accepted jurisdiction. The Board would make its determination within 30 days after receipt of an appropriately documented request for an expedited review determination.

[47 FR 31690, July 22, 1982, as amended at 48 FR 22925, May 23, 1983]

§405.1843 Parties to Board hearing.

(a) The parties to the Board hearing shall be the provider, the intermediary (including the Centers for Medicare & Medicaid Services when acting directly as intermediary) that rendered the determination being appealed (see §405.1833), and any other entity found by the intermediary to be a related organization of such provider.

(b) Except as provided in paragraph (a), neither the Secretary nor the Centers for Medicare & Medicaid Services may be made a party to the hearing. However, the Board may call as a witness any employee or officer of the Department of Health and Human Services having personal knowledge of the facts and the issues in controversy in a hearing pending before the Board and may call as a consultant to the Board in connection with any such hearing any individual designated by the Secretary for such purpose. (See §405.1863.)

§405.1845 Composition of Board.

(a) The Board will consist of five members appointed by the Secretary. All shall be knowledgeable in the field of cost reimbursement. At least one shall be a certified public accountant. Two Board members shall be representative of providers of services.

(b) The term of office for Board members shall be 3 years, except that initial appointments may be for such shorter terms as the Secretary may designate to permit staggered terms of office. No member shall serve more than two consecutive 3-year terms of office. The Secretary shall have the authority to terminate a Board member's term of office for good cause.

(c) One member of the Board shall be designated by the Secretary as Chairman thereof and shall coordinate and direct the administrative activities of the Board, and shall have such other authority which may be granted to him by the Board.

(d) A quorum shall be required for the rendering of Board decisions. Three members, at least one of whom is representative of providers of services, shall be required to constitute a quorum. The Chairman of the Board, with approval of the provider, may designate one or more Board members to conduct any hearing and to prepare a recommended decision (where less than a quorum conducts the hearing). (See §405.1869.)

[39 FR 34515, Sept. 26, 1974, as amended at 41 FR 52051, Nov. 26, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§405.1847 Disqualification of Board members.

No Board member shall join in the conduct of a hearing in a case in which he is prejudiced or partial with respect to any party or in which he has any interest in the matter pending for decision before him. Notice of any objection which a party may have with respect to a Board member shall be presented in writing to such Board member by the objecting party at its earliest opportunity. The Board member shall consider the objection and shall, in his discretion, either proceed to join

in the conduct of the hearing or withdraw. If he does not withdraw, the objecting party may petition the Board, presenting its objection and reasons therefor, and be entitled to a ruling thereon before the hearing can proceed.

§ 405.1849 Establishment of time and place of hearing by the Board.

The Board shall fix the time and place for the hearing and shall mail written notice thereof to the parties at their last known addresses, not less than 30 days prior to the scheduled time. Either on its own motion or for good cause shown by a party, the Board may, as appropriate, reschedule, adjourn, postpone, or reopen the hearing, provided that reasonable written notice is given to the parties.

§ 405.1851 Conduct of Board hearing.

The Board hearing shall be open to the parties, to representatives of the Centers for Medicare & Medicaid Services, and to such other persons as the Board deems necessary and proper. The Board shall inquire fully into all of the matters at issue and shall receive into evidence the testimony of witnesses and any documents which are relevant and material to such matters. If the Board believes that there is relevant and material evidence available which has not been presented at the hearing, it may at any time prior to the mailing of notice of the decision, reconvene the hearing for the receipt of such evidence. The order in which the evidence and the allegations shall be presented and the conduct of the hearing shall be at the discretion of the Board.

§ 405.1853 Prehearing discovery and other proceedings prior to the Board hearing.

(a) Upon notification that a request for Board hearing has been filed, the intermediary shall forthwith review the materials submitted by the provider in accordance with § 405.1841. Simultaneously, the intermediary shall review the information which formed the basis for its determination of the amount of program reimbursement. Based on the findings of such review, the intermediary shall expeditiously attempt to join with the provider in written stipulations setting forth the issues that said review has resolved and designating the issues that remain for Board resolution. Having obtained such stipulations and being satisfied that no further agreements can be negotiated, the intermediary shall ensure that all available documentary evidence in support of each party's position is part of the record. Such evidence will ordinarily include a position paper from the provider, a position paper from the intermediary, and any documents which support the issues addressed in the stipulations. These materials, in addition to all relevant documents which formed the basis for its determination of the amount of program reimbursement, shall be forwarded to the Board within 60 days after the date of the provider's request for Board review.

(b) Prehearing discovery shall be permitted upon timely request of a party. To be timely, a request for discovery and inspection shall be made before the beginning of the hearing. A reasonable time for inspection and reproduction of documents shall be provided by order of the Board. The Board's order on all discovery matters shall be final.

(c) If, in the discretion of the Board, the purpose of defining the issues more clearly would be served, the Board may schedule a prehearing conference. For this purpose, a single member of the Board may be appointed to act for the Board with respect to prehearing activities.

§ 405.1855 Evidence at Board hearing.

Evidence may be received at the Board hearing even though inadmissible under the rules of evidence applicable to court procedure. The Board shall give the parties opportunity for submission and consideration of facts and arguments and during the course of the hearing should, in ruling upon admissibility of evidence, exclude irrelevant, immaterial, or unduly repetitious evidence. The Board shall render a final ruling on the admissibility of evidence.

§ 405.1857 Subpoenas.

When reasonably necessary for the full presentation of a case, the Board may, either upon its own motion or

upon the request of a party, issue subpoenas for the attendance and testimony of witnesses and for the production of books, records, correspondence, papers, or other documents which are relevant and material to any matter in issue at the hearing. Parties who desire the issuance of a subpoena shall, not less than 10 days prior to the time fixed for the hearing, file with the Board a written request therefor, designating the witnesses or documents to be produced, and describing the address, or location thereof with sufficient particularity to permit such witnesses or documents to be found. The request for a subpoena shall state the pertinent facts which the party expects to establish by such witnesses or documents and whether such facts could be established by other evidence without the use of a subpoena. Subpoenas, as provided for above, shall be issued in the name of the Board, and the Centers for Medicare & Medicaid Services shall assume the cost of the issuance and the fees and mileage of any witness so subpoenaed, as provided in section 205(d) of the Act, 42 U.S.C. 405(d).

§405.1859 Witnesses.

Witnesses at the hearing shall testify under oath or affirmation, unless excused by the Board for cause. The Board may examine the witnesses and shall allow the parties or their representatives to do so. Parties to the proceeding may also cross-examine witnesses.

§405.1861 Oral argument and written allegations.

The parties, upon their request, shall be allowed a reasonable time for the presentation of oral argument or for the filing of briefs or other written statements of allegations as to facts or law. Copies of any brief or other written statement shall be filed in sufficient number that they may be made available to all parties and to the Centers for Medicare & Medicaid Services.

§405.1863 Administrative policy at issue.

Where a party to the Board hearing puts into issue an administrative policy which is interpretative of the law or regulations, the Board will promptly notify to the Centers for Medicare & Medicaid Services.

§405.1865 Record of Board hearing.

A complete record of the proceedings at the hearing shall be made and transcribed in all cases. It shall be made available to the parties upon request. The record will not be closed until a decision has been issued.

§405.1867 Sources of Board's authority.

In exercising its authority to conduct the hearings described herein, the Board must comply with all the provisions of title XVIII of the Act and regulations issued thereunder, as well as CMS Rulings issued under the authority of the Administrator of the Centers for Medicare & Medicaid Services (see §401.108 of this subchapter). The Board shall afford great weight to interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

[48 FR 22925, May 23, 1983]

§405.1869 Scope of Board's decision-making authority.

The Board shall have the power to affirm, modify, or reverse a determination of an intermediary with respect to a cost report and to make any other modifications on matters covered by such cost report (including modifications adverse to the provider or other parties) even though such matters were not considered in the intermediary's determination. The opinion of the majority of those Board members deciding the case will constitute the Board's decision.

§405.1871 Board hearing decision and notice.

(a) The Board shall, as soon as practicable after the conclusion of its hearing, render a written decision based upon the record made at such hearing, the record established in support of the determination of the intermediary (see §405.1803), and such other evidence as may be obtained or received by the Board. Such Board decision shall be supported by substantial evidence when the record of the Board hearing is

viewed as a whole and shall cite applicable law, regulations, and CMS Rulings. A copy of the decision shall be mailed to all parties to the hearing at their last known addresses and, at the same time, to the Administrator and CMS.

(b) The decision of the Board provided for in paragraph (a) of this section shall be final and binding upon all parties to the hearing before the Board unless it is reviewed by the Secretary in accordance with § 405.1875, or revised in accordance with § 405.1885.

[39 FR 34515, Sept. 26, 1974, as amended at 41 FR 52051, Nov. 26, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 48 FR 45773, Oct. 7, 1983]

§ 405.1873 Board's jurisdiction.

(a) *Board decides jurisdiction.* The Board decides questions relating to its jurisdiction to grant a hearing, including (1) the timeliness of an intermediary determination (see § 405.1835(c)), and (2) the right of a provider to a hearing before the Board when the amount in controversy is in issue (see §§ 405.1835(a)(3) and 405.1837).

(b) *Matters not subject to board review.* (1) The determination of a fiscal intermediary that no payment may be made under title XVIII of the Act for any expenses incurred for items and services furnished to an individual because such items and services are excluded from coverage pursuant to section 1862 of the Act, 42 U.S.C. 1395y (see subpart C of this part), may not be reviewed by the Board. (Such determination shall be reviewed only in accordance with the applicable provisions of subpart G or H of this part.)

(2) The Board may not review certain matters affecting payments to hospitals under the prospective payment system as provided in § 405.1804.

[48 FR 39836, Sept. 1, 1983]

§ 405.1875 Administrator's review.

(a) *General rule.* (1) Except for a Board determination under § 405.1842 that it lacks the authority to decide an issue, the Administrator, at his or her discretion, may review any final decision of the Board, including a decision under § 405.1873 about the Board's jurisdiction to grant a hearing. The Administrator may exercise this discretion on his or her own motion, in response to a request from a party to a Board hearing or in response to a request from CMS.

(2) The Office of the Attorney Advisory will examine the Board's decisions, the requests made by a party or CMS and any submission made in accordance with the provisions of this section in order to assist the Administrator in deciding whether to exercise this review authority.

(b) *Request for review.* A party or CMS requesting the Administrator to review a Board decision must file a written request with the Administrator within 15 days of the receipt of the Board decision.

(c) *Criteria for deciding whether to review.* In deciding whether to review a Board decision, either on his or her own motion or in response to a request from a party to the hearing or CMS, the Administrator will normally consider whether it appears that:

(1) The Board made an erroneous interpretation of law, regulation or CMS Ruling;

(2) The Board's decision is not supported by substantial evidence; or

(3) The case presents a significant policy issue having a basis in law and regulations, and review is likely to lead to the issuance of a CMS Ruling or other directive needed to clarify a statutory or regulatory provision;

(4) The Board has incorrectly assumed or denied jurisdiction or extended its authority to a degree not provided for by statute, regulation or CMS Ruling; and

(5) The decision of the Board requires clarification, amplification, or an alternative legal basis for the decision.

(d) *Decision to review.* (1) Whether or not a party or CMS has requested review, the Administrator will promptly notify the parties and CMS whether he or she has decided to review a decision of the Board and, if so, will indicate the particular issues he or she will consider.

(2) The Administrator may decline to review a case or any issue in a case even if a party has filed a written request for review under paragraph (b) of this section.

(e) *Written submissions.* (1) Within 15 days of receipt of a notice that the Administrator has decided to review a Board decision, a party or CMS may submit to the Administrator, in writing:

(i) Proposed findings and conclusions;

(ii) Supporting views or exceptions to the Board decision;

(iii) Supporting reasons for the exceptions and proposed findings; and

(iv) A rebuttal of the other party's request for review or other submissions already filed with the Administrator.

(2) These submissions shall be limited to issues the Administrator has decided to review and confined to the record of the Board hearing.

(3) A party or CMS, within 15 days of receipt of a notice that the Administrator has decided to review a decision, may also request that the decision be remanded and state reasons for doing so. Reasons for a request to remand may include new, substantial evidence concerning—

(i) Issues presented to the Board; and

(ii) New issues that have arisen since the case was presented to the Board.

(4) A copy of any written submission made under this paragraph shall be sent simultaneously to each other party to the Board hearing and to CMS, if CMS has previously—

(i) Requested that the Administrator review a Board decision or filed a written submission in response to a party's request for review.

(ii) Responded to a party's request for review; or

(iii) Submitted material after the Administrator has announced that he or she will review a Board decision.

(f) *Ex parte communications prohibited.* All communications from any of the parties or CMS about a Board decision being reviewed by the Administrator must be in writing and must contain a certification that copies have been served on the parties and CMS, as appropriate. The Administrator will not consider any communication that does not meet these requirements or is not submitted within the required time limits.

(g) *Administrator's decision.* (1) If the Administrator has notified the parties and CMS that he or she has decided to review a Board decision, the Administrator will affirm, reverse, modify or remand the case.

(2) The Administrator will make this decision within 60 days after the provider received notification of the Board decision and will promptly mail a copy of the decision to each party and to CMS.

(3) Any decision other than to remand will be confined to—

(i) The record of the Board, as forwarded by the Board;

(ii) Any materials submitted under paragraphs (b) or (e) of this section; and

(iii) Generally known facts that are not subject to reasonable dispute.

(4) The Administrator may rely on prior decisions of the Board, the Administrator and the courts, and other applicable law, whether or not cited by the parties and CMS.

(h) *Remand.* (1) A remand to the Board by the Administrator vacates the Board's decision.

(2) The Administrator may direct the Board to take further action with respect to the development of additional facts or new issues, or to consider the applicability of laws or regulations other than those considered by the Board. The following are not acceptable bases for remand—

(i) Presentation of evidence existing at the time of the Board hearing that was known or reasonably could have been known;

(ii) Introduction of a favorable court case that was either not available in print at the time of the Board hearing or was decided after the Board hearing;

(iii) Change of a party's representation before the Board;

(iv) Presentation of an alternative legal basis concerning an issue in dispute; or

(v) Attempted retraction of a waiver of a right made before or at the Board hearing.

(3) After remand, the Board will take the action requested in the remand action and issue a new decision.

(4) The new decision will be final unless the Administrator reverses, affirms, modifies, or again remands the decision in accordance with the provisions of the section.

[48 FR 45773, Oct. 7, 1983]

§ 405.1877 Judicial review.

(a) *General rule.* Section 1878(f) of the Act permits a provider to obtain judicial review of a final decision of the Board, or of a reversal, affirmation, or modification by the Administrator of a Board decision, by filing a civil action pursuant to the Federal Rules of Civil Procedure within 60 days of the date on which the provider received notice of—

(1) A final decision by the Board; or

(2) Any reversal, affirmance, or modification by the Administrator.

The Board's decision is not final if the Administrator reverses, affirms or modifies the decision within 60 days of the date on which the provider received notice of the decision.

(b) *Administrator declines to review a Board decision.* If the Administrator declines to review a Board decision, the provider must file its appeal within 60 days of receipt of the decision of the Board.

(c) *Administrator does not act after reviewing a Board decision.* If the Administrator notifies the parties that he or she has decided to review a Board decision and then does not make a decision within the 60 days allotted for his or her review, this subsequent inaction constitutes an affirmance allowing a provider an additional 60 days in which to file for judicial review, beginning with the date the Administrator's time expires for taking action under § 405.1875(g)(2).

(d) *Matters not subject to judicial review.* Certain matters affecting payments to hospital under the prospective payment system are not subject to judicial review, as provided in section 1886(d)(7) of the Act and § 405.1804.

(e) *Group appeals.* Any action under this section by providers that are under common ownership or control (see § 413.17 of this chapter) must be brought by the providers as a group with respect to any matter involving an issue common to the providers.

(f) *Venue for appeals.* An action for judicial review must be brought in the District Court of the United States for the judicial district in which the provider is located (or, effective April 20, 1983, in an action brought jointly by several providers, the judicial district in which the greatest number of such providers are located) or in the District Court for the District of Columbia. Effective April 20, 1983, any action for judicial review by providers under common ownership or control (§ 413.17 of this chapter), must be brought by such providers as a group with respect to any matter involving an issue common to the providers.

(g) *Service of process.* Process must be served as described under 45 CFR part 4.

[48 FR 39836, Sept. 1, 1983, as amended at 48 FR 45774, Oct. 7, 1983; 51 FR 34793, Sept. 30, 1986]

§ 405.1881 Appointment of representative.

A provider or other party may be represented by legal counsel or any other person it appoints to act as its representative at the proceedings, conducted in accordance with §§ 405.1819 and 405.1851.

§ 405.1883 Authority of representative.

A representative appointed by a provider or other party may accept or give on behalf of the provider or other party any request or notice relative to any proceeding before a hearing officer or the Board. A representative shall be entitled to present evidence and allegations as to facts and law in any proceeding affecting the party he represents and to obtain information with respect to a request for an intermediary hearing or a Board hearing made in accordance with §§ 405.1811, 405.1835, or 405.1837 to the same extent as the party he represents. Notice to a provider or other party of any action, determination, or decision, or a request for the production of evidence by a hearing officer or the Board sent to the representative of the provider or other party shall have the same force and effect as if it had been sent to the provider or other party.

§ 405.1885 Reopening a determination or decision.

(a) A determination of an intermediary, a decision by a hearing officer or panel of hearing officers, a decision by the Board, or a decision of the Secretary may be reopened with respect to

findings on matters at issue in such determination or decision, by such intermediary officer or panel of hearing officers, Board, or Secretary, as the case may be, either on motion of such intermediary officer or panel of hearing officers, Board, or Secretary, or on the motion of the provider affected by such determination or decision to revise any matter in issue at any such proceedings. Any such request to reopen must be made within 3 years of the date of the notice of the intermediary or Board hearing decision, or where there has been no such decision, any such request to reopen must be made within 3 years of the date of notice of the intermediary determination. No such determination or decision may be reopened after such 3-year period except as provided in paragraphs (d) and (e) of this section.

(b)(1) An intermediary determination or an intermediary hearing decision must be reopened and revised by the intermediary if, within the 3-year period specified in paragraph (a) of this section, CMS—

(i) Provides notice to the intermediary that the intermediary determination or the intermediary hearing decision is inconsistent with the applicable law, regulations, CMS ruling, or CMS general instructions in effect, and as CMS understood those legal provisions, at the time the determination or decision was rendered by the intermediary; and

(ii) Explicitly directs the intermediary to reopen and revise the intermediary determination or the intermediary hearing decision.

(2) A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening an intermediary determination or an intermediary hearing decision under this section.

(3) Notwithstanding paragraph (b)(1)(i) of this section, CMS may direct the intermediary to reopen a particular intermediary determination or intermediary hearing decision in order to implement, for the same intermediary determination or intermediary decision—

(i) A final agency decision under §§405.1833, 405.1871(b), 405.1875, or 405.1877(a) of this part;

(ii) A final nonappealable court judgment; or

(iii) An agreement to settle an administrative appeal or a lawsuit.

(c) Jurisdiction for reopening a determination or decision rests exclusively with that administrative body that rendered the last determination or decision.

(d) Notwithstanding the provisions of paragraph (a) of this section, an intermediary determination or hearing decision, a decision of the Board, or a decision of the Secretary shall be reopened and revised at any time if it is established that such determination or decision was procured by fraud or similar fault of any party to the determination or decision.

(e) Notwithstanding an intermediary's discretion to reopen or not reopen an intermediary determination or an intermediary hearing decision under paragraphs (a) and (c) of this section, CMS may direct an intermediary to reopen, or not to reopen, an intermediary determination or an intermediary hearing decision in accordance with paragraphs (a) and (c) of this section.

(f) Paragraphs (a) and (b) of this section apply to determinations on cost reporting periods ending on or after December 31, 1971. (See §405.1801(c).) However, the 3-year period described shall also apply to determinations with respect to cost reporting periods ending prior to December 31, 1971, but only if the reopening action was undertaken after May 27, 1972 (the effective date of regulations which, prior to the publication of this subpart R, governed the reopening of such determinations).

[39 FR 34515, Sept. 26, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 50110, Aug. 1, 2002]

§405.1887 Notice of reopening.

(a) All parties to any reopening described above shall be given written notice of the reopening. When such reopening results in any revision in the prior decision notice of said revision or revisions will be mailed to the parties with a complete explanation of the

basis for the revision or revisions. Notices of reopenings by the Board shall also be sent to the Secretary.

(b) In any such reopening, the parties to the prior decision shall be allowed a reasonable period of time in which to present any additional evidence or argument in support of their position.

§ 405.1889 Effect of a revision.

Where a revision is made in a determination or decision on the amount of program reimbursement after such determination or decision has been reopened as provided in § 405.1885, such revision shall be considered a separate and distinct determination or decision to which the provisions of §§ 405.1811, 405.1835, 405.1875 and 405.1877 are applicable. (See § 405.1801(c) for applicable effective dates.)

Subparts S–T [Reserved]

Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

AUTHORITY: Secs. 1102, 1138, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b–8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

SOURCE: 41 FR 22511, June 3, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.2100 Scope of subpart.

(a) The regulations in this subpart prescribe the role which End-Stage Renal Disease (ESRD) networks have in the ESRD program, establish the mechanism by which minimal utilization rates are promulgated and applied, under section 1881(b)(1) of the Act, and describe the health and safety requirements that facilities furnishing ESRD care to beneficiaries must meet. These regulations further prescribe the role of ESRD networks in meeting the requirements of section 1881(c) of the Act.

(b) The general objectives of the ESRD program are contained in § 405.2101, and general definitions are contained in § 405.2102. The provisions of §§ 405.2110, 405.2112 and 405.2113 discuss the establishment and activities of ESRD networks, network organizations and membership requirements and restrictions for members of the medical review boards. Sections 405.2120 through 405.2124 discuss the establishment of minimal utilization rates and the requirements for approval of facilities with respect to such rates. Sections 405.2130 through 405.2140 discuss general requirements for, and description of, all facilities furnishing ESRD services. Sections 405.2160 through 405.2164 discuss specific requirements for facilities which furnish ESRD dialysis services. Sections 405.2170 and 405.2171 discuss specific requirements for facilities which furnish ESRD transplantation services.

[51 FR 30361, Aug. 26, 1986]

§ 405.2101 Objectives of the end-stage renal disease (ESRD) program.

The objectives of the end-stage renal disease program are:

(a) To assist beneficiaries who have been diagnosed as having end-stage renal disease (ESRD) to receive the care they need;

(b) To encourage proper distribution and effective utlization of ESRD treatment resources while maintaining or improving the quality of care;

(c) To provide the flexibility necessary for the efficient delivery of appropriate care by physicians and facilities; and

(d) To encourage self-dialysis or transplantation for the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for such treatment.

[43 FR 48950, Oct. 19, 1979]

§ 405.2102 Definitions.

As used in this subpart, the following definitions apply:

Agreement. A written document executed between an ESRD facility and another facility in which the other facility agrees to assume responsibility for furnishing specified services to patients and for obtaining reimbursement for those services.

Arrangement. A written document executed between an ESRD facility and another facility in which the other facility agrees to furnish specified services to patients but the ESRD facility

retains responsibility for those services and for obtaining reimbursement for them.

Dialysis. A process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

End-Stage Renal Disease (ESRD). That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD facility. A facility which is approved to furnish at least one specific ESRD service (see definition of ''ESRD service''). Such facilities are:

(a) *Renal dialysis center.* A hospital unit which is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement). A hospital need not provide renal transplantation to qualify as a renal dialysis center.

(b) *Renal dialysis facility.* A unit which is approved to furnish dialysis service(s) directly to ESRD patients.

(c) *Self-dialysis unit.* A unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility, and furnishes self-dialysis services.

(d) *Special purpose renal dialysis facility.* A renal dialysis facility which is approved under §405.2164 to furnish dialysis at special locations on a short-term basis to a group of dialysis patients otherwise unable to obtain treatment in the geographical area. The special locations must be either special rehabilitative (including vacation) locations serving ESRD patients temporarily residing there, or locations in need of ESRD facilities under emergency circumstances.

ESRD service. The type of care or services furnished to an ESRD patient. Such types of care are:

(a) *Dialysis service*—(1) *Inpatient dialysis.* Dialysis which, because of medical necessity, is furnished to an ESRD patient on a temporary inpatient basis in a hospital;

(2) *Outpatient dialysis.* Dialysis furnished on an outpatient basis at a renal dialysis center or facility. Outpatient dialysis includes:

(i) *Staff-assisted dialysis.* Dialysis performed by the staff of the center or facility.

(ii) *Self-dialysis.* Dialysis performed, with little or no professional assistance, by an ESRD patient who has completed an appropriate course of training.

(3) *Home dialysis.* Dialysis performed by an appropriately trained patient at home.

(b) *Self-dialysis and home dialysis training.* A program that trains ESRD patients to perform self-dialysis or home dialysis with little or no professional assistance, and trains other individuals to assist patients in performing self-dialysis or home dialysis.

Furnishes directly. The ESRD facility provides the service through its own staff and employees, or through individuals who are under direct contract to furnish such services personally for the facility (i.e., not through ''agreements'' or ''arrangements'').

Furnishes on the premises. The ESRD facility furnishes services on its main premises; or on its other premises that are (a) contiguous with or in immediate proximity to the main premises, and under the direction of the same professional staff and governing body as the main premises, or (b) approved on a time-limited basis as a special purpose renal dialysis facility.

Medical care criteria. Predetermined elements against which aspects of the quality of a medical service may be compared. They are developed by professionals relying on professional expertise and on the professional literature.

Medical care norms. Numerical or statistical measures of usual observed performance. Norms are derived from aggregate information related to the health care provided to a large number of patients over a period of time.

Medical care standards. Professionally developed expressions of the range of acceptable variation from a norm or criterion.

Medical care evaluation study (*MCE*). Review of health care services, usually performed retrospectively, in which an indepth assessment of the quality and/or utilization of such services is made.

Network, ESRD. All Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

Network organization. The administrative governing body to the network and liaison to the Federal government.

Qualified personnel. Personnel that meet the requirements specified in this paragraph.

(a) *Chief executive officer.* A person who:

(1) Holds at least a baccalaureate degree or its equivalent and has at least 1 year of experience in an ESRD unit; or

(2) Is a registered nurse or physician director as defined in this definition; or

(3) As of September 1, 1976, has demonstrated capability by acting for at least 2 years as a chief executive officer in a dialysis unit or transplantation program.

(b) *Dietitian.* A person who:

(1) Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976, and has at least 1 year of experience in clinical nutrition; or

(2) Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition.

(c) *Medical record practitioner.* A person who:

(1) Has graduated from a program for Medical Record Administrators accredited by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as a Registered Record Administrator (RRA) by the American Medical Record Association under its requirements in effect on June 3, 1976.

(2) Has graduated from a program for Medical Record Technicians approved jointly by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as an Accredited Record Technician (ART) by the American Medical Record Association under its requirements in effect June 3, 1976, or

(3) Has successfully completed and received a satisfactory grade in the American Medical Record Association's Correspondence Course for Medical Record Personnel approved by the Accrediting Commission of the National Home Study Council, and is eligible for certification as an Accredited Record Technician by the American Medical Record Association under its requirements in effect June 3, 1976.

(d) *Nurse responsible for nursing service.* A person who is licensed as a registered nurse by the State in which practicing, and (1) has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process; or

(2) Has 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process;

(3) If the nurse responsible for nursing service is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience is in training patients in self-care.

(e) *Physician-director.* A physician who:

(1) Is board eligible or board certified in internal medicine or pediatrics by a professional board, and has had at least 12 months of experience or training in the care of patients at ESRD facilities; or

(2) During the 5-year period prior to September 1, 1976, served for at least 12 months as director of a dialysis or transplantation program;

(3) In those areas where a physician who meets the definition in paragraph (1) or (2) of this definition is not available to direct a participating dialysis facility, another physician may direct the facility, subject to the approval of the Secretary.

(f) *Social worker.* A person who is licensed, if applicable, by the State in which practicing, and

(1) Has completed a course of study with specialization in clinical practice

at, and holds a masters degree from, a graduate school of social work accredited by the Council on Social Work Education; or

(2) Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under paragraph (f)(1) of this definition.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48950, Oct. 19, 1978; 51 FR 30361, Aug. 26, 1986; 53 FR 6547, Mar. 1, 1988; 55 FR 9575, Mar. 14, 1990; 72 FR 15273, Mar. 30, 2007]

§405.2110 Designation of ESRD networks.

CMS designated ESRD networks in which the approved ESRD facilities collectively provide the necessary care for ESRD patients.

(a) *Effect on patient choice of facility.* The designation of networks does not require an ESRD patient to seek care only through the facilities in the designated network where the patient resides, nor does the designation of networks limit patient choice of physicians or facilities, or preclude patient referral by physicians to a facility in another designated network.

(b) *Redesignation of networks.* CMS will redesignate networks, as needed, to ensure that the designations are consistent with ESRD program experience, consistent with ESRD program objectives specified in §405.2101, and compatible with efficient program administration.

[51 FR 30361, Aug. 26, 1986]

§405.2111 [Reserved]

§405.2112 ESRD network organizations.

CMS will designate an administrative governing body (network organization) for each network. The functions of a network organization include but are not limited to the following:

(a) Developing network goals for placing patients in settings for self-care and transplantation.

(b) Encouraging the use of medically appropriate treatment settings most compatible with patient rehabilitation and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs.

(c) Developing criteria and standards relating to the quality and appropriateness of patient care and, with respect to working with patients, facilities, and providers of services, for encouraging participation in vocational rehabilitation programs.

(d) Evaluating the procedures used by facilities in the network in assessing patients for placement in appropriate treatment modalities.

(e) Making recommendations to member facilities as needed to achieve network goals.

(f) On or before July 1 of each year, submitting to CMS an annual report that contains the following information:

(1) A statement of the network goals.

(2) The comparative performance of facilities regarding the placement of patients in appropriate settings for—

(i) Self-care;

(ii) Transplants; and

(iii) Vocational rehabilitation programs.

(3) Identification of those facilities that consistently fail to cooperate with the goals specified under paragraph (f)(1) of this section or to follow the recommendations of the medical review board.

(4) Identification of facilities and providers that are not providing appropriate medical care.

(5) Recommendations with respect to the need for additional or alternative services in the network including self-dialysis training, transplantation and organ procurement.

(g) Evaluating and resolving patient grievances.

(h) Appointing a network council and a medical review board (each including at least one patient representative) and supporting and coordinating the activities of each.

(i) Conducting on-site reviews of facilities and providers as necessary, as determined by the medical review board or CMS, using standards of care as specified under paragraph (c) of this section.

(j) Collecting, validating, and analyzing such data as necessary to prepare the reports required under paragraph (f) of this section and the Secretary's report to Congress on the ESRD program and to assure the maintenance of the registry established under section 1881(c)(7) of the Act.

[53 FR 1620, Jan. 21, 1988]

§ 405.2113 Medical review board.

(a) *General.* The medical review board must be composed of physicians, nurses, and social workers engaged in treatment relating to ESRD and qualified to evaluate the quality and appropriateness of care delivered to ESRD patients, and at least one patient representative.

(b) *Restrictions on medical review board members.* (1) A medical review board member must not review or provide advice with respect to any case in which he or she has, or had, any professional involvement, received reimbursement or supplied goods.

(2) A medical review board member must not review the ESRD services of a facility in which he or she has a direct or indirect financial interest (as described in section 1126(a)(1) of the Act).

[51 FR 30361, Aug. 26, 1986, as amended at 53 FR 1620, Jan. 21, 1988]

§ 405.2114 [Reserved]

§ 405.2131 Condition: Provider status: Renal transplantation center or renal dialysis center.

A renal transplantation center or a renal dialysis center (§ 405.2102(e) (1) or (2)) operated by a hospital may qualify for approval and be reimbursed under the ESRD program only if the hospital is otherwise an approved provider in the Medicare program.

§ 405.2132 [Reserved]

§ 405.2133 Condition: Furnishing data and information for ESRD program administration.

The ESRD facility, laboratory performing histocompatibility testing, and organ procurement organization furnishes data and information in the manner and at the intervals specified by the Secretary, pertaining to its ESRD patient care activities and costs, for inclusion in a national ESRD medical information system and in compilations relevant to program administration, including claims processing and reimbursement. Such information is treated as confidential when it pertains to individual patients and is not disclosed except as authorized by Department regulations on confidentiality and disclosure (see 45 CFR parts 5, 5b, and part 401 of this chapter).

[53 FR 6548, Mar. 1, 1988]

§ 405.2134 Condition: Participation in network activities.

Each facility must participate in network activities and pursue network goals.

[51 FR 30362, Aug. 26, 1986]

§ 405.2135 Condition: Compliance with Federal, State and local laws and regulations.

The ESRD facility is in compliance with applicable Federal, State and local laws, and regulations.

(a) *Standard: licensure.* Where State or applicable local law provides for the licensing of ESRD facilities, the facility is:

(1) Licensed pursuant to such law; or

(2) Approved by the agency of such State or locality responsible for such licensing as meeting the standards established for such licensing.

(b) *Standard: licensure or registration of personnel.* Each staff member is currently licensed or registered in accordance with applicable law.

(c) *Standard: conformity with other laws.* The facility is in conformity with applicable laws and regulations pertaining to fire safety, equipment, and other relevant health and safety requirements.

§ 405.2136 Condition: Governing body and management.

The ESRD facility is under the control of an identifiable governing body, or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance

and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility. The governing body receives and acts upon recommendations from the network organization. The governing body appoints a chief executive officer who is responsible for the overall management of the facility.

(a) *Standard: disclosure of ownership.* The ESRD facility supplies full and complete information to the State survey agency (§405.1902(a)) as to the identity of:

(1) Each person who has any direct or indirect ownership interest of 10 per centum or more in the facility, or who is the owner (in whole or in part) of any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the facility or any of the property or assets of the facility;

(2) Each officer and director of the corporation, if the facility is organized as a corporation; and

(3) Each partner, if the facility is organized as a partnership; and promptly reports to the State survey agency any changes which would affect the current accuracy of the information so required to be supplied.

(b) *Standard: Operational objectives.* The operational objectives of the ESRD facility, including the services that it provides, are established by the governing body and delineated in writing. The governing body adopts effective administrative rules and regulations that are designed to safeguard the health and safety of patients and to govern the general operations of the facility, in accordance with legal requirements. Such rules and regulations are in writing and dated. The governing body ensures that they are operational, and that they are reviewed at least annually and revised as necessary. If the ESRD facility is engaged in the practice of hemodialyzer reuse, the governing body ensures that there are written policies and procedures with respect to reuse, to assure that recommended standards and conditions are being followed, and requires that patients be informed of the policies and procedures.

(1) The objectives of the facility are formulated in writing and clearly stated in documents appropriate for distribution to patients, facility personnel, and the public.

(2) A description of the services provided by the facility, together with a categorical listing of the types of diagnostic and therapeutic procedures that may be performed, is readily available upon request to all concerned.

(3) Admission criteria that insure equitable access to services are adopted by the facility and are readily available to the public. Access to the self-dialysis unit is available only to patients for whom the facility maintains patient care plans (see §405.2137).

(4) The operational objectives and administrative rules and regulations of the facility are reviewed at least annually and revised as necessary by the administrative staff, medical director, and other appropriate personnel of the facility, and are adopted when approved by the governing body.

(c) *Standard: chief executive officer.* The governing body appoints a qualified chief executive officer who, as the ESRD facility's administrator: Is responsible for the overall management of the facility; enforces the rules and regulations relative to the level of health care and safety of patients, and to the protection of their personal and property rights; and plans, organizes, and directs those responsibilities delegated to him by the governing body. Through meetings and periodic reports, the chief executive officer maintains on-going liaison among the governing body, medical and nursing personnel, and other professional and supervisory staff of the facility, and acts upon recommendations made by the medical staff and the governing body. In the absence of the chief executive officer, a qualified person is authorized in writing to act on the officer's behalf.

(1) The governing body delineates in writing the responsibilities of the chief executive officer, and ensures that he/she is sufficiently free from other duties to provide effective direction and management of the operations and fiscal affairs of the facility.

(2) The chief executive officer serves on a full-time or part-time basis, in accordance with the scope of the facility's operations and administrative

needs, and devotes sufficient time to the conduct of such responsibilities.

(3) The responsibilities of the chief executive officer include but are not limited to:

(i) Implementing the policies of the facility and coordinating the provision of services, in accordance with delegations by the governing body.

(ii) Organizing and coordinating the administrative functions of the facility, redelegating duties as authorized, and establishing formal means of accountability for those involved in patient care.

(iii) Authorizing expenditures in accordance with established policies and procedures.

(iv) Familiarizing the staff with the facility's policies, rules, and regulations, and with applicable Federal, State, and local laws and regulations.

(v) Maintaining and submitting such records and reports, including a chronological record of services provided to patients, as may be required by the facility's internal committees and governing body, or as required by the Secretary.

(vi) Participating in the development, negotiation, and implementation of agreements or contracts into which the facility may enter, subject to approval by the governing body of such agreements or contracts.

(vii) Participating in the development of the organizational plan and ensuring the development and implementation of an accounting and reporting system, including annual development of a detailed budgetary program, maintenance of fiscal records, and quarterly submission to the governing body of reports of expenses and revenues generated through the facility's operation.

(viii) Ensuring that the facility employs the number of qualified personnel needed; that all employees have appropriate orientation to the facility and their work responsibilities upon employment; and that they have an opportunity for continuing education and related development activities.

(d) *Standard: personnel policies and procedures.* The governing body, through the chief executive officer of the ESRD facility, is responsible for maintaining and implementing written personnel policies and procedures that support sound patient care and promote good personnel practices. These policies and procedures ensure that:

(1) All members of the facility's staff are qualified to perform the duties and responsibilities assigned to them and meet such Federal, State, and local professional requirements as may apply.

(2) A safe and sanitary environment for patients and personnel exists, and reports of incidents and accidents to patients and personnel are reviewed to identify health and safety hazards. Health supervision of personnel is provided, and they are referred for periodic health examinations and treatments as necessary or as required by Federal, State, and local laws. Procedures are established for routine testing to ensure detection of hepatitis and other infectious diseases.

(3) If the services of trainees are utilized in providing ESRD services, such trainees are under the direct supervision of qualified professional personnel.

(4) Complete personnel records are maintained on all personnel. These include health status reports, resumes of training and experience, and current job descriptions that reflect the employees' responsibilities and work assignments.

(5) Personnel policies are written and made available to all personnel in the facility. The policies provide for an effective mechanism to handle personnel grievances.

(6) All personnel of the facility participate in educational programs on a regular basis. These programs cover initial orientation, and continuing in-service training, including procedures for infection control. Records are maintained showing the content of training sessions and the attendance at such sessions.

(7) Personnel manuals are maintained, periodically updated, and made available to all personnel involved in patient care.

(e) *Standard: use of outside resources.* If the ESRD facility makes arrangements for the provision of a specific service as authorized in this subpart, the responsibilities, functions, objectives, and the terms of each arrangement, including financial provisions

and charges, are delineated in a document signed by an authorized representative of the facility and the person or agency providing the service. The chief executive officer when utilizing outside resource, as a consultant, assures that he is apprised of recommendations, plans for implementation, and continuing assessment through dated, signed reports, which are retained by the chief executive officer for follow-up action and evaluation of performance.

(f) *Standard: patient care policies.* The ESRD facility has written policies, approved by the governing body, concerning the provision of dialysis and other ESRD services to patients. The governing body reviews implementation of policies periodically to ensure that the intent of the policies is carried out. These policies are developed by the physician responsible for supervising and directing the provision of ESRD services, or the facility's organized medical staff (if there is one), with the advice of (and with provision for review of such policies from time to time, but at least annually, by) a group of professional personnel associated with the facility, including, but not limited to, one or more physicians and one or more registered nurses experienced in rendering ESRD care.

(1) The patient care policies cover the following:

(i) Scope of services provided by the facility (either directly or under arrangement).

(ii) Admission and discharge policies (in relation to both in-facility care and home care).

(iii) Medical supervision and physician services.

(iv) Patient long term programs, patient care plans and methods of implementation.

(v) Care of patients in medical and other emergencies.

(vi) Pharmaceutical services.

(vii) Medical records (including those maintained in the ESRD facility and in the patients' homes, to ensure continuity of care).

(viii) Administrative records.

(ix) Use and maintenance of the physical plant and equipment.

(x) Consultant qualifications, functions, and responsibilities.

(xi) The provision of home dialysis support services, if offered (see §405.2163(e)).

(2) The physician-director of the facility is designated in writing to be responsible for the execution of patient care policies. If the responsibility for day-to-day execution of patient care policies has been delegated by a physican director to (or, in the case of a self-dialysis unit, to another licensed health practitioner) a registered nurse, the physican-director provides medical guidance in such matters.

(3) The facility policy provides that, whenever feasible, hours for dialysis are scheduled for patient convenience and that arrangements are made to accommodate employed patients who wish to be dialyzed during their nonworking hours.

(4) The governing body adopts policies to ensure there is evaluation of the progress each patient is making toward the goals stated in the patient's long term program and patient's care plan (see §405.2137(a)). Such evaluations are carried out through regularly scheduled conferences, with participation by the staff involved in the patient's care.

(g) *Standard: medical supervision and emergency coverage.* The governing body of the ESRD dialysis and/or transplant facility ensures that the health care of every patient is under the continuing supervision of a physician and that a physician is available in emergency situations.

(1) The physician responsible for the patient's medical supervision evaluates the patient's immediate and long-term needs and on this basis prescribes a planned regimen of care which covers indicated dialysis and other ESRD treatments, services, medications, diet, special procedures recommended for the health and safety of the patient, and plans for continuing care and discharge. Such plans are made with input from other professional personnel involved in the care of the patient.

(2) The governing body ensures that there is always available medical care for emergencies, 24 hours a day, 7 days a week. There is posted at the nursing/monitoring station a roster with the names of the physicians to be called, when they are available for emergencies, and how they can be reached.

(h) *Standard: medical staff.* The governing body of the ESRD facility designates a qualified physician (see § 405.2102) as director of the ESRD services; the appointment is made upon the recommendation of the facility's organized medical staff, if there is one. The governing body establishes written policies regarding the development, negotiation, consummation, evaluation, and termination of appointments to the medical staff.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 48952, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986; 52 FR 36934, Oct. 2, 1987]

§ 405.2137 Condition: Patient long-term program and patient care plan.

Each facility maintains for each patient a written long-term program and a written patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within that modality. The patient, or where appropriate, parent or legal guardian is involved with the health team in the planning of care. A copy of the current program and plan accompany the patient on interfacility transfer.

(a) *Standard: patient long-term program.* There is a written long-term program representing the selection of a suitable treatment modality (i.e., dialysis or transplantation) and dialysis setting (e.g., home, self-care) for each patient.

(1) The program is developed by a professional team which includes but is not limited to the physician director of the dialysis facility or center where the patient is currently being treated, a physician director of a center or facility which offers self-care dialysis training (if not available at the location where the patient is being treated), a transplant surgeon, a qualified nurse responsible for nursing services, a qualified dietitian and a qualified social worker.

(2) The program is formally reviewed and revised in writing as necessary by a team which includes but is not limited to the physician director of the dialysis facility or center where the patient is presently being treated, in addition to the other personnel listed in paragraph (a)(1) of this section at least every 12 months or more often as indicated by the patient's response to treatment (see § 405.2161(b)(1) and § 405.2170(a)).

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the patient's long-term program, and due consideration is given to his preferences.

(4) A copy of the patient's long-term program accompanies the patient on interfacility transfer or is sent within 1 working day.

(b) *Standard: patient care plan.* There is a written patient care plan for each patient of an ESRD facility (including home dialysis patients under the supervision of the ESRD facility; see § 405.2163(e)), based upon the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs.

(1) The patient care plan is personalized for the individual, reflects the psychological, social, and functional needs of the patient, and indicates the ESRD and other care required as well as the individualized modifications in approach necessary to achieve the long-term and short-term goals.

(2) The plan is developed by a professional team consisting of at least the physician responsible for the patient's ESRD care, a qualified nurse responsible for nursing services, a qualified social worker, and a qualified dietitian.

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the care plan, and due consideration is given to his preferences.

(4) The care plan for patients whose medical condition has not become stabilized is reviewed at least monthly by the professional patient care team described in paragraph (b)(2) of this section. For patients whose condition has become stabilized, the care plan is reviewed every 6 months. The care plan is revised as necessary to insure that it provides for the patients ongoing needs.

(5) If the patient is transferred to another facility, the care plan is sent with the patient or within 1 working day.

(6) For a home-dialysis patient whose care is under the supervision of the

ESRD facility, the care plan provides for periodic monitoring of the patient's home adaptation, including provisions for visits to the home by qualified facility personnel to the extent appropriate. (See §405.2163(e).)

(7) Beginning July 1, 1991, for a home dialysis patient, and beginning January 1, 1994, for any dialysis patient, who uses EPO in the home, the plan must provide for monitoring home use of EPO that includes the following:

(i) Review of diet and fluid intake for indiscretions as indicated by hyperkalemia and elevated blood pressure secondary to volume overload.

(ii) Review of medications to ensure adequate provision of supplemental iron.

(iii) Ongoing evaluations of hematocrit and iron stores.

(iv) A reevaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume.

(v) A method for physician followup on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results.

(vi) Training of the patient to identify the signs and symptoms of hypotension and hypertension.

(vii) The decrease or discontinuance of EPO if hypertension is uncontrollable.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 59 FR 1284, Jan. 10, 1994; 59 FR 26958, May 25, 1994]

§405.2138 Condition: Patients' rights and responsibilities.

The governing body of the ESRD facility adopts written policies regarding the rights and responsibilities of patients and, through the chief executive officer, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures are made available to patients and any guardians, next of kin, sponsoring agency(ies), representative payees (selected pursuant to section 205(j) of the Social Security Act and subpart Q of 20 CFR part 404), and to the public. The staff of the facility is trained and involved in the execution of such policies and procedures. The patients' rights policies and procedures ensure at least the following:

(a) *Standard: informed patients.* All patients in the facility:

(1) Are fully informed of these rights and responsibilities, and of all rules and regulations governing patient conduct and responsibilities;

(2) Are fully informed of services available in the facility and of related charges including any charges for services not covered under title XVIII of the Social Security Act;

(3) Are fully informed by a physician of their medical condition unless medically contraindicated (as documented in their medical records);

(4) Are fully informed regarding the facility's reuse of dialysis supplies, including hemodialyzers. If printed materials such as brochures are utilized to describe a facility and its services, they must contain a statement with respect to reuse; and

(5) Are fully informed regarding their suitability for transplantation and home dialysis.

(b) *Standard: participation in planning.* All patients treated in the facility:

(1) Are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research;

(2) Are transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for nonpayment of fees (except as prohibited by title XVIII of the Social Security Act), and are given advance notice to ensure orderly transfer or discharge.

(c) *Standard: respect and dignity.* All patients are treated with consideration, respect, and full recognition of their individuality and personal needs, including the need for privacy in treatment. Provision is made for translators where a significant number of patients exhibit language barriers.

(d) *Standard: confidentiality.* All patients are ensured confidential treatment of their personal and medical records, and may approve or refuse release of such records to any individual outside the facility, except in case of their transfer to another health care institution or as required by Federal, State, or local law and the Secretary for proper administration of the program.

(e) *Standard: grievance mechanism.* All patients are encouraged and assisted to understand and exercise their rights. Grievances and recommended changes in policies and services may be addressed to facility staff, administration, the network organization, and agencies or regulatory bodies with jurisdiction over the facility, through any representative of the patient's choice, without restraint or interference, and without fear of discrimination or reprisal.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 52 FR 36934, Oct. 2, 1987]

§ 405.2139 Condition: Medical records.

The ESRD facility maintains complete medical records on all patients (including self-dialysis patients within the self-dialysis unit and home dialysis patients whose care is under the supervision of the facility) in accordance with accepted professional standards and practices. A member of the facility's staff is designated to serve as supervisor of medical records services, and ensures that all records are properly documented, completed, and preserved. The medical records are completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.

(a) *Standard: medical record.* Each patient's medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately. All medical records contain the following general categories of information: Documented evidence of assessment of the needs of the patient, whether the patient is treated with a reprocessed hemodialyzer, of establishment of an appropriate plan of treatment, and of the care and services provided (see § 405.2137(a) and (b)); evidence that the patient was informed of the results of the assessment described in § 405.2138(a)(5); identification and social data; signed consent forms referral information with authentication of diagnosis; medical and nursing history of patient; report(s) of physician examination(s); diagnostic and therapeutic orders; observations, and progress notes; reports of treatments and clinical findings; reports of laboratory and other diagnostic tests and procedures; and discharge summary including final diagnosis and prognosis.

(b) *Standard: protection of medical record information.* The ESRD facility safeguards medical record information against loss, destruction, or unauthorized use. The ESRD facility has written policies and procedures which govern the use and release of information contained in medical records. Written consent of the patient, or of an authorized person acting in behalf of the patient, is required for release of information not provided by law. Medical records are made available under stipulation of confidentiality for inspection by authorized agents of the Secretary, as required for administration of the ESRD program under Medicare.

(c) *Standard: medical records supervisor.* A member of the ESRD facility's staff is designated to serve as supervisor of the facility's medical records service. The functions of the medical records supervisor include, but are not limited to, the following: Ensuring that the records are documented, completed, and maintained in accordance with accepted professional standards and practices; safeguarding the confidentiality of the records in accordance with established policy and legal requirements; ensuring that the records contain pertinent medical information and are filed for easy retrieval. When necessary, consultation is secured from a qualified medical record practitioner.

(d) *Standard: Completion of medical records and centralization of clinical information.* Current medical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's medical record. Provision is made for collecting and including in the medical record medical information generated by self-dialysis patients. Entries concerning the daily dialysis process may either be completed by staff, or be completed by trained self-dialysis patients, trained home dialysis patients or trained assistants and countersigned by staff.

(e) *Standard: retention and preservation of records.* Medical records are retained for a period of time not less than that determined by the State statute governing records retention or statute of limitations; or in the absence of a State statute, 5 years from the date of discharge; or, in the case of a minor, 3 years after the patient becomes of age under State law, whichever is longest.

(f) *Standard: location and facilities.* The facility maintains adequate facilities, equipment, and space conveniently located, to provide efficient processing of medical records (e.g., reviewing, filing, and prompt retrieval) and statistical medical information (e.g., required abstracts, reports, etc.).

(g) *Standard: transfer of medical information.* The facility provides for the interchange of medical and other information necessary or useful in the care and treatment of patients transferred between treating facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 52 FR 36934, Oct. 2, 1987]

§405.2140 Condition: Physical environment.

The physical environment in which ESRD services are furnished affords a functional, sanitary, safe, and comfortable setting for patients, staff, and the public.

(a) *Standard: building and equipment.* The physical structure in which ESRD services are furnished is constructed, equipped, and maintained to insure the safety of patients, staff, and the public.

(1) Fire extinguishers are conveniently located on each floor of the facility and in areas of special hazard. Fire regulations and fire management procedures are prominently posted and properly followed.

(2) All electrical and other equipment used in the facility is maintained free of defects which could be a potential hazard to patients or personnel. There is established a planned program of preventive maintenance of equipment used in dialysis and related procedures in the facility.

(3) The areas used by patients are maintained in good repair and kept free of hazards such as those created by damaged or defective parts of the building.

(4) [Reserved]

(5)(i) The ESRD facility must employ the water quality requirements listed in paragraph (a)(5)(ii) of this section developed by the Association for the Advancement of Medical Instrumentation (AAMI) and published in ''Hemodialysis Systems,'' second edition, which is incorporated by reference.

(ii) Required water quality requirements are those listed in sections 3.2.1, Water Bacteriology; 3.2.2, Maximum Level of Chemical Contaminants; and in Appendix B: Guideline for Monitoring Purity of Water Used for Hemodialysis as B1 through B5.

(iii) Incorporation by reference of the AAMI's ''Hemodialysis Systems,'' second edition, 1992, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.[1] If any changes in ''Hemodialysis Systems,'' second edition, are also to be incorporated by reference, a notice to that effect will be published in the FEDERAL REGISTER.

(b) *Standard: favorable environment for patients.* The facility is maintained and equipped to provide a functional sanitary, and comfortable environment with an adequate amount of well-lighted space for the service provided.

(1) There are written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to, appropriate procedures for surveillance and reporting of infections, housekeeping, handling and disposal of waste and contaminants, and

[1] The publication entitled ''Hemodialysis Systems,'' second edition, 1992, is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD 21244–1850 and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

sterilization and disinfection, including the sterilization and maintenance of equipment where dialysis supplies are reused, there are written policies and procedures covering the rinsing, cleaning, disinfection, preparation and storage of reused items which conform to requirements for reuse in § 405.2150.

(2) Treatment areas are designed and equipped to provide adequate and safe dialysis therapy, as well as privacy and comfort for patients. The space for treating each patient is sufficient to accomodate medically needed emergency equipment and staff and to ensure that such equipment and staff can reach the patient in an emergency. There is sufficient space in units for safe storage of self-dialysis supplies.

(3) There is a nursing/monitoring station from which adequate surveillance of patients receiving dialysis services can be made.

(4) Heating and ventilation systems are capable of maintaining adequate and comfortable temperatures.

(5) Each ESRD facility utilizing a central-batch delivery system provides, either on the premises or through affiliation agreement or arrangement (see § 405.2160) sufficient individual delivery systems for the treatment of any patient requiring special dialysis solutions.

(c) *Standard contamination prevention.* The facility employs appropriate techniques to prevent cross-contamination between the unit and adjacent hospital or public areas including, but not limited to, food service areas, laundry, disposal of solid waste and blood-contaminated equipment, and disposal of contaminants into sewage systems. Waste storage and disposal are carried out in accordance with applicable local laws and accepted public health procedures. The written patient care policies (see § 405.2136(f)(1)) specify the functions that are carried out by facility personnel and by the self-dialysis patients with respect to contamination prevention. Where dialysis supplies are reused, records are maintained that can be used to determine whether established procedures covering the rinsing, cleaning, disinfection, preparation and storage of reused items, conform to requirements for reuse in § 405.2150.

(d) *Standard: emergency preparedness.* Written policies and procedures specifically define the handling of emergencies which may threaten the health or safety of patients. Such emergencies would exist during a fire or natural disaster or during functional failures in equipment. Specific emergency preparedness procedures exist for different kinds of emergencies. These are reviewed and tested at least annually and revised as necessary by, or under the direction of, the chief executive officer. All personnel are knowledgeable and trained in their respective roles in emergency situations.

(1) There is an established written plan for dealing with fire and other emergencies which, when necessary, is developed in cooperation with fire and other expert personnel.

(2) All personnel are trained, as part of their employment orientation, in all aspects of preparedness for any emergency or disaster. The emergency preparedness plan provides for orientation and regular training and periodic drills for all personnel in all procedures so that each person promptly and correctly carries out a specified role in case of an emergency.

(3) There is available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies, and equipment, and staff are trained in its use.

(4) The staff is familiar with the use of all dialysis equipment and procedures to handle medical emergencies.

(5) Patients are trained to handle medical and nonmedical emergencies. Patients must be fully informed regarding what to do, where to go, and whom to contact if a medical or nonmedical emergency occurs.

(Secs. 1102, 1871, 1881(b), Social Security Act; 42 U.S.C. 1302, 1395hh, 1395rr(b))

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 45 FR 24839, Apr. 10, 1980; 52 FR 36934, Oct. 2, 1987; 60 FR 48043, Sept. 18, 1995; 69 FR 18803, Apr. 9, 2004]

§ 405.2150 Condition: Reuse of hemodialyzers and other dialysis supplies.

An ESRD facility that reuses hemodialyzers and other dialysis supplies meets the requirements of this

section. Failure to meet any of paragraphs (a) through (c) of this section constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program.

(a) *Standard: Hemodialyzers.* If the ESRD facility reuses hemodialyzers, it conforms to the following:

(1) *Reuse guidelines.* Voluntary guidelines adopted by the AAMI (''Reuse of Hemodialyzers,'' second edition). Incorporation by reference of the AAMI's ''Reuse of Hemodialyzers,'' second edition, 1993, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.[1] If any changes in ''Reuse of Hemodialyzers,'' second edition, are also to be incorporated by reference, a notice to that effect will be published in the FEDERAL REGISTER.

(2) *Procedure for chemical germicides.* To prevent any risk of dialyzer membrane leaks due to the combined action of different chemical germicides, dialyzers are exposed to only one chemical germicide during the reprocessing procedure. If a dialyzer is exposed to a second germicide, the dialyzer must be discarded.

(3) *Surveillance of patient reactions.* In order to detect bacteremia and to maintain patient safety when unexplained events occur, the facility—

(i) Takes appropriate blood cultures at the time of a febrile response in a patient; and

(ii) If pyrogenic reactions, bacteremia, or unexplained reactions associated with ineffective reprocessing are identified, terminates reuse of hemodialyzers in that setting and does not continue reuse until the entire reprocessing system has been evaluated.

(b) *Standard: Transducer filters.* To control the spread of hepatitis, transducer filters are changed after each dialysis treatment and are not reused.

(c) *Standard: Bloodlines.* If the ESRD facility reuses bloodlines, it must—

(1) Limit the reuse of bloodlines to the same patient;

(2) Not reuse bloodlines labeled for ''single use only'';

(3) Reuse only bloodlines for which the manufacturer's protocol for reuse has been accepted by the Food and Drug Administration (FDA) pursuant to the premarket notification (section 510(k)) provision of the Food, Drug, and Cosmetic Act; and

(4) Follow the FDA-accepted manufacturer's protocol for reuse of that bloodline.

[52 FR 36935, Oct. 2, 1987, as amended at 55 FR 18335, May 2, 1990; 60 FR 48044, Sept. 18, 1995; 69 FR 18803, Apr. 9, 2004]

§405.2160 Condition: Affiliation agreement or arrangement.

(a) A renal dialysis facility and a renal dialysis center (see §405.2102(e)(2)) have in effect an affiliation agreement or arrangement with each other, in writing, for the provision of inpatient care and other hospital services.

(b) The affiliation agreement or arrangement provides the basis for effective working relationships under which inpatient hospital care or other hospital services are available promptly to the dialysis facility's patients when needed. The dialysis facility has in its files documentation from the renal dialysis center to the effect that patients from the dialysis facility will be accepted and treated in emergencies. There are reasonable assurances that:

(1) Transfer or referral of patients will be effected between the renal dialysis center and the dialysis facility whenever such transfer or referral is determined as medically appropriate by the attending physician, with timely acceptance and admission;

(2) There will be interchange, within 1 working day, of the patient long-term program and patient care plan, and of medical and other information necessary or useful in the care and treatment of patients transferred or referred

[1] The publication entitled ''Reuse of Hemodialyzers,'' second edition, 1993, is available for inspection at the CMS Information Resources Center, 7500 Security Boulevard, Baltimore, MD 21244–1850 and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

between the facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities; and

(3) Security and accountability for patients' personal effects are assured.

§ 405.2161 Condition: Director of a renal dialysis facility or renal dialysis center.

Treatment is under the general supervision of a Director who is a physician. The physician-director need not devote full time as Director but is responsible for planning, organizing, conducting, and directing the professional ESRD services and must devote sufficient time to carrying out these responsibilities. The director may also serve as the Chief Executive Officer of the facility.

(a) *Standard: qualifications.* The director of a dialysis facility is a qualified physician-director. (See § 405.2102.)

(b) *Standard: responsibilities.* The responsibilities of the physician-director include but are not limited to the following:

(1) Participating in the selection of a suitable treatment modality, i.e., transplantation or dialysis, and dialysis setting, for all patients;

(2) Assuring adequate training of nurses and technicians in dialysis techniques;

(3) Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks;

(4) Assuring the development and availability of a patient care policy and procedures manual and its implementation. As a minimum, the manual describes the types of dialysis used in the facility and the procedures followed in performance of such dialysis; hepatitis prevention and procedures for handling an individual with hepatitis; and a disaster preparedness plan (e.g., patient emergency, fire, flood); and

(5) When self-dialysis training or home dialysis training is offered, assuring that patient teaching materials are available for the use of all trainees during training and at times other than during the dialysis procedure.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986]

§ 405.2162 Condition: Staff of a renal dialysis facility or renal dialysis center.

Properly trained personnel are present in adequate numbers to meet the needs of the patients, including those arising from medical and nonmedical emergencies.

(a) *Standard: Registered nurse.* The dialysis facility employs at least one full time qualified nurse responsible for nursing service. (See § 405.2102.)

(b) *Standard: On-duty personnel.* Whenever patients are undergoing dialysis:

(1) One currently licensed health professional (e.g., physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care;

(2) An adequate number of personnel are present so that the patient/staff ratio is appropriate to the level of dialysis care being given and meets the needs of patients; and

(3) An adequate number of personnel are readily available to meet medical and nonmedical needs.

(c) *Standard: Self-care dialysis training personnel.* If the facility offers self-care dialysis training, a qualified nurse is in charge of such training (see § 405.2102.)

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48953, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986]

§ 405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center.

The facility must provide dialysis services, as well as adequate laboratory, social, and dietetic services to meet the needs of the ESRD patient.

(a) *Standard: Outpatient dialysis services*—(1) *Staff-assisted dialysis services.* The facility must provide all necessary institutional dialysis services and staff required in performing the dialysis.

(2) *Self-dialysis services.* If the facility offers self-dialysis services, it must provide all medically necessary supplies and equipment and any other

service specified in the facility's patient care policies.

(b) *Standard: Laboratory services.* The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. All laboratory services must be performed by an appropriately certified laboratory in accordance with part 493 of this chapter. If the renal dialysis facility furnishes its own laboratory services, it must meet the applicable requirements established for certification of laboratories found in part 493 of this chapter. If the facility does not provide laboratory services, it must make arrangements to obtain these services from a laboratory certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.

(c) *Standard: Social services.* Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (§405.2102) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.

(d) *Standard: Dietetic services.* Each patient is evaluated as to his nutritional needs by the attending physician and by a qualified dietician (§405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.

(e) *Standard: Self-dialysis support services.* The renal dialysis facility or center furnishing self-dialysis training upon completion of the patient's training, furnishes (either directly, under agreement or by arrangement with another ESRD facility) the following services:

(1) Surveillance of the patient's home adaptation, including provisions for visits to the home or the facility;

(2) Consultation for the patient with a qualified social worker and a qualified dietitian;

(3) A recordkeeping system which assures continuity of care;

(4) Installation and maintenance of equipment;

(5) Testing and appropriate treatment of the water; and

(6) Ordering of supplies on an ongoing basis.

(f) *Standard: Participation in recipient registry.* The dialysis facility or center participates in a patient registry program with an OPO designated or redesignated under part 486, subpart G of this chapter, for patients who are awaiting cadaveric donor transplantation.

(g) *Use of EPO at home: Patient selection.* The dialysis facility, or the physician responsible for all dialysis-related services furnished to the patient, must make a comprehensive assessment that includes the following:

(1) *Pre-selection monitoring.* The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.

(2) *Conditions the patient must meet.* The assessment must find that the patient meets the following conditions:

(i) On or after July 1, 1991, is a home dialysis patient or, on or after January 1, 1994, is a dialysis patient;

(ii) Has a hematocrit (or comparable hemoglobin level) that is as follows:

(A) For a patient who is initiating EPO treatment, no higher than 30 percent unless there is medical documentation showing the need for EPO despite a hematocrit (or comparable hemoglobin level) higher than 30 percent. (Patients with severe angina, severe pulmonary distress, or severe hypertension may require EPO to prevent adverse symptoms even if they have

higher hematocrit or hemoglobin levels.)

(B) For a patient who has been receiving EPO from the facility or the physician, between 30 and 33 percent.

(iii) Is under the care of—

(A) A physician who is responsible for all dialysis-related services and who prescribes the EPO and follows the drug labeling instructions when monitoring the EPO home therapy; and

(B) A renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO therapy.

(3) *Conditions the patient or the patient's caregiver must meet.* The assessment must find that the patient or a caregiver who assists the patient in performing self-dialysis meets the following conditions:

(i) Is trained by the facility to inject EPO and is capable of carrying out the procedure.

(ii) Is capable of reading and understanding the drug labeling.

(iii) Is trained in, and capable of observing, aseptic techniques.

(4) *Care and storage of drug.* The assessment must find that EPO can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child's having access to the drug and syringes.

(h) *Use of EPO at home: Responsibilities of the physician or the dialysis facility.* The patient's physician or dialysis facility must—

(1) Develop a protocol that follows the drug label instructions;

(2) Make the protocol available to the patient to ensure safe and effective home use of EPO; and

(3) Through the amounts prescribed, ensure that the drug ''on hand'' at any time does not exceed a 2-month supply.

[43 FR 48953, Oct. 19, 1978, as amended at 51 FR 30362, Aug. 26, 1986; 57 FR 7134, Feb. 28, 1992; 59 FR 1284, Jan. 10, 1994; 59 FR 26958, May 25, 1994; 59 FR 46513, Sept. 8, 1994; 61 FR 19743, May 2, 1996]

§ 405.2164 Conditions for coverage of special purpose renal dialysis facilities.

(a) A special purpose renal dialysis facility must comply with all conditions for coverage for renal dialysis facilities specified in §§ 405.2130 through 405.2164, with the exception of §§ 405.2134, and 405.2137 that relate to participation in the network activities and patient long-term programs.

(b) A special purpose renal dialysis facility must consult with a patient's physician to assure that care provided in the special purpose dialysis facility is consistent with the patient's long-term program and patient care plan required under § 405.2137.

(c) The period of approval for a special purpose renal dialysis facility may not exceed 8 calendar months in any calendar year.

(d) A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility.

[48 FR 21283, May 11, 1983, as amended at 51 FR 30362, Aug. 26, 1986]

§ 405.2180 Termination of Medicare coverage.

(a) Except as provided in § 405.2181, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in this subpart U will result in termination of Medicare coverage of the services furnished by that supplier.

(b) If termination of coverage is based solely on a supplier's failure to participate in network activities and pursue network goals, as required by § 405.2134, coverage may be reinstated when CMS determines that the supplier is making reasonable and appropriate efforts to meet that condition.

(c) If termination of coverage is based on failure to meet any of the other conditions specified in this subpart, coverage will not be reinstated until CMS finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.

[53 FR 36277, Sept. 19, 1988]

§ 405.2181 Alternative sanctions.

(a) *Basis for application of alternative sanctions.* CMS may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if CMS finds that—

(1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass its geographic area; and

(2) This failure does not jeopardize patient health and safety.

(b) *Alternative sanctions.* The alternative sanctions that CMS may apply in the circumstances specified in paragraph (a) of this section include the following:

(1) Denial of payment for services furnished to patients first accepted for care after the effective date of sanction as specified in the sanction notice.

(2) Reduction of payments, for all ESRD services furnished by the supplier, by 20 percent for each 30-day period after the effective date of sanction.

(3) Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries.

(c) *Duration of sanction.* An alternative sanction remains in effect until CMS finds that the supplier is in substantial compliance with the requirement to cooperate in the network plans and goals, or terminates coverage of the supplier's services for lack of compliance.

[53 FR 36277, Sept. 19, 1988]

§405.2182 Notice of sanction and appeal rights: Termination of coverage.

(a) *Notice of sanction.* CMS gives the supplier and the general public notice of sanction and of the effective date of the sanction. The effective date of the sanction is at least 30 days after the date of the notice.

(b) *Appeal rights.* Termination of Medicare coverage of a supplier's ESRD services because the supplier no longer meets the conditions for coverage of its services is an initial determination appealable under part 498 of this chapter.

[53 FR 36277, Sept. 19, 1988]

§405.2184 Notice of appeal rights: Alternative sanctions.

If CMS proposes to apply a sanction specified in §405.2181(b), the following rules apply:

(a) CMS gives the facility notice of the proposed sanction and 15 days in which to request a hearing.

(b) If the facility requests a hearing, CMS provides an informal hearing by a CMS official who was not involved in making the appealed decision.

(c) During the informal hearing, the facility—

(1) May be represented by counsel;

(2) Has access to the information on which the allegation was based; and

(3) May present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network activities and pursue network goals.

(d) If the written decision of the informal hearing supports application of the alternative sanction, CMS provides the facility and the public, at least 30 days before the effective date of the sanction, with a written notice that specifies the effective date and the reasons for the sanction.

[53 FR 36277, Sept. 19, 1988]

Subparts V–W [Reserved]

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 43 FR 8261, Mar. 1, 1978, unless otherwise noted.

§405.2400 Basis.

Subpart X is based on the provisions of the following sections of the Act: Section 1833 sets forth the amounts of payment for supplementary medical insurance services. Section 1861(aa) sets forth the rural health clinic services and Federally qualified health center services covered by the Medicare program.

[60 FR 63176, Dec. 8, 1995]

§405.2401 Scope and definitions.

(a) *Scope.* This subpart establishes the requirements for coverage and reimbursement of rural health clinic and Federally qualified health center services under Medicare.

(b) *Definitions.* As used in this subpart, unless the context indicates otherwise:

Act means the Social Security Act.

Allowable costs means costs that are incurred by a clinic or center and are reasonable in amount and proper and necessary for the efficient delivery of rural health clinic and Federally qualified health center services.

Beneficiary means an individual enrolled in the Supplementary Medical Insurance program for the Aged and Disabled (part of title XVIII of the Act).

Coinsurance means that portion of the clinic's charge for covered services for which the beneficiary is liable in addition to the deductible.

Carrier means an organization that has a contract with the Secretary to administer the benefits covered by this subpart.

Covered services means items or services for which the beneficiary is entitled to have payment made on his or her behalf under this subpart.

Deductible means:

(1) The first $100 of expenses incurred by the beneficiary during any calendar year for items and services covered under Part B of title XVIII; and

(2) The expenses incurred for the first 3 pints of blood or 3 units of packed red blood cells furnished to a beneficiary during any calendar year. (See §§ 410.160 and 410.161 of this chapter for greater detail.)

Federally qualified health center (FQHC) means an entity that has entered into an agreement with CMS to meet Medicare program requirements under §§ 405.2434 and—

(1) Is receiving a grant under section 329, 330, or 340 of the Public Health Service Act, or is receiving funding from such a grant under a contract with the recipient of such a grant and meets the requirements to receive a grant under section 329, 330 or 340 of the Public Health Service Act;

(2) Based on the recommendation of the PHS, is determined by CMS to meet the requirements for receiving such a grant;

(3) Was treated by CMS, for purposes of part B, as a comprehensive federally funded health center (FFHC) as of January 1, 1990; or

(4) Is an outpatient health program or facility operated by a tribe or tribal organizations under the Indian Self-Determination Act or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

CMS stands for Centers for Medicare & Medicaid Services.

Intermittent nursing care means a medically predictable need for nursing care from time to time, but usually not less frequently than once every 60 days.

Nurse-midwife means a registered professional nurse who meets the following requirements:

(1) Is currently licensed to practice in the State as a registered professional nurse.

(2) Is legally authorized under State law or regulations to practice as a nurse-midwife.

(3) Except as provided in paragraph (b)(10)(iv) of this section, has completed a program of study and clinical experience for nurse-midwives, as specified by the State.

(4) If the State does not specify a program of study and clinical experience that nurse-midwives must complete to practice in that State, meets one of the following conditions:

(i) Is currently certified as a nurse-midwife by the American College of Nurse-Midwives.

(ii) Has satisfactorily completed a formal education program (of at least one academic year) that, upon completion, qualifies the nurse to take the certification examination offered by the American College of Nurse-Midwives.

(iii) Has successfully completed a formal educational program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and was practicing as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976 to July 16, 1982.

Nurse practitioner and *physician assistant* means individuals who meet the applicable education, training experience and other requirements of § 491.2 of this chapter.

Part-time nursing care means nursing care that is required on less than a

full-time basis, that is, less than 8 hours a day or 40 hours a week.

Physician means the following:

(1) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which the function is performed.

(2) Within limitations as to the specific services furnished, a doctor of dentistry or dental or oral surgery, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor. (See section 1861(r) of the Act for specific limitations.)

(3) A resident (including residents as defined in §415.152 of this chapter who meet the requirements in §415.206(b) of this chapter for payment under the physician fee schedule).

Reporting period means a period of 12 consecutive months specified by the intermediary as the period for which a clinic or center must report its costs and utilization. The first and last reporting periods may be less than 12 months.

Rural health clinic means a facility that:

(1) Has been determined by the Secretary to meet the requirements of section 1861(aa)(2) of the Act and part 491 of this chapter; and

(2) Has filed an agreement with the Secretary in order to provide rural health clinic services under Medicare. (See §405.2402.)

Secretary means the Secretary of Health and Human Services or his delegate.

Visiting nurse services means part-time or intermittent nursing care and related medical supplies (other than drugs or biologicals) furnished by a registered nurse or licensed practical nurse to a homebound patient.

(Secs. 1102, 1833, 1861(aa), 1871, 1902(a)(13), Social Security Act; 49 Stat. 647, 79 Stat. 302, 322, and 331, 91 Stat. 1485 (42 U.S.C. 1302, 1395*l*, 1395hh, 1395x(aa), and 1396(a)(13))

[43 FR 8261, Mar. 1, 1978, as amended at 43 FR 30526, July 14, 1978; 47 FR 21049, May 17, 1982; 47 FR 23448, May 28, 1982; 51 FR 41351, Nov. 14, 1986; 57 FR 24975, June 12, 1992; 59 FR 26958, May 25, 1994; 60 FR 63176, Dec. 8, 1995; 61 FR 14657, Apr. 3, 1996; 69 FR 74815, Dec. 24, 2003; 71 FR 55345, Sept. 22, 2006]

§405.2402 Basic requirements.

(a) *Certification by the State survey agency.* The rural health clinic must be certified in accordance with part 491 of this chapter.

(b) *Acceptance of the clinic as qualified to furnish rural health clinic services.* If the Secretary, after reviewing the survey agency recommendation and other evidence relating to the qualifications of the rural health clinic, determines that it meets the requirements of this subpart and of part 491 of this chapter, he will send the clinic:

(1) Written notice of the determination; and

(2) Two copies of the agreement to be filed as required by section 1861(aa)(1) of the Act.

(c) *Filing of agreement by the rural health clinic.* If the rural health clinic wishes to participate in the program, it must:

(1) Have both copies of the agreement signed by an authorized representative; and

(2) File them with the Secretary.

(d) *Acceptance by the Secretary.* If the Secretary accepts the agreement filed by the rural health clinic, he will return to the clinic one copy of the agreement, with a notice of acceptance specifying the effective date.

(e) *Duration of agreement.* The agreement shall be for a term of one year and may be renewed annually by mutual consent of the Secretary and the rural health clinic.

(f) *Appeal rights.* If the Secretary does not certify a rural health clinic, or refuses to enter into or renew an agreement, the facility is entitled to a hearing in accordance with part 498 of this chapter.

[43 FR 8261, Mar. 1, 1978, as amended at 52 FR 22454, June 12, 1987]

§405.2403 Content and terms of the agreement with the Secretary.

(a) Under the agreement, the rural health clinic agrees to the following:

(1) *Maintaining compliance with conditions.* The clinic agrees to maintain compliance with the conditions set forth in part 491 of this chapter and to report promptly to CMS any failure to do so.

(2) *Charges to beneficiaries.* The clinic agrees not to charge the beneficiary or

any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of this part (or for which the beneficiary would have been entitled if the rural health clinic had filed a request for payment in accordance with § 410.165 of this chapter), except for any deductible or coinsurance amounts for which the beneficiary is liable under § 405.2410.

(3) *Refunds to beneficiaries.* (i) The clinic agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(ii) As used in this section, *money incorrectly collected* means sums collected in excess of the amount for which the beneficiary was liable under § 405.2410. It includes amounts collected at a time when the beneficiary was believed not to be entitled to Medicare benefits but:

(A) The beneficiary is later determined to have been entitled to Medicare benefits; and

(B) The beneficiary's entitlement period falls within the time the rural health clinic's agreement with the Secretary is in effect.

(4) *Beneficiary treatment.* (i) The clinic agrees to accept beneficiaries for care and treatment; and

(ii) The clinic agrees not to impose any limitations on the acceptance of beneficiaries for care and treatment that it does not impose on all other persons.

(b) *Additional provisions.* The agreement may contain any additional provisions that the Secretary finds necessary or desirable for the efficient and effective administration of the Medicare program.

[43 FR 8261, Mar. 1, 1978, as amended at 51 FR 41351, Nov. 14, 1986]

§ 405.2404 Terminations of agreements.

(a) *Termination by rural health clinic*—(1) *Notice to Secretary.* If the clinic wishes to terminate its agreement it shall file with the Secretary a written notice stating the intended effective date of termination.

(2) *Action by the Secretary.* (i) The Secretary may approve the date proposed by the clinic, or set a different date no later than 6 months after the date of the clinic's notice.

(ii) The Secretary may approve a date which is less than 6 months after the date of notice if he determines that termination on that date would not:

(A) Unduly disrupt the furnishing of services to the community serviced by the clinic; or

(B) Otherwise interfere with the effective and efficient administration of the Medicare program.

(3) *Cessation of business.* If a clinic ceases to furnish services to the community, that shall be deemed to be a voluntary termination of the agreement by the clinic, effective on the last day of business.

(b) *Termination by the Secretary*—(1) *Cause for termination.* The Secretary may terminate an agreement if he determines that the rural health clinic:

(i) No longer meets the conditions for certification under part 491 of this chapter; or

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, any other applicable regulations of this part, or any applicable provisions of title XVIII of the Act; or

(iii) Has undergone a change of ownership.

(2) *Notice of termination.* The Secretary will give notice of termination to the rural health clinic at least 15 days before the effective date stated in the notice.

(3) *Appeal by the rural health clinic.* A rural health clinic may appeal the termination of its agreement in accordance with the provisions set forth in part 498 of this chapter.

(c) *Effect of termination.* Payment will not be available for rural health clinic services furnished on or after the effective date of termination.

(d) *Notice to the public.* Prompt notice of the date and effect of termination shall be given to the public, through publication in local newspapers:

(1) By the clinic, after the Secretary has approved or set a termination date; or

(2) By the Secretary, when he has terminated the agreement.

(e) *Conditions for reinstatement after termination of agreement by the Secretary.* When an agreement with a rural health clinic is terminated by the Secretary, the rural health clinic may not

file another agreement to participate in the Medicare program unless the Secretary:

(1) Finds that the reason for the termination of the prior agreement has been removed; and

(2) Is assured that the reason for the termination will not recur.

[43 FR 8261, Mar. 1, 1978, as amended at 52 FR 22454, June 12, 1987]

§405.2410 Application of Part B deductible and coinsurance.

(a) *Application of deductible.* (1) Medicare payment for rural health clinic services begins only after the beneficiary has incurred the deductible.

(2) Medicare payment for services covered under the Federally qualified health center benefit is not subject to the usual Part B deductible.

(b) *Application of coinsurance.* (1) The beneficiary is responsible for a coinsurance amount which cannot exceed 20 percent of the clinic's reasonable customary charge for the covered service; and

(2)(i) The beneficiary's deductible and coinsurance liability, with respect to any one item or service furnished by the rural health clinic, may not exceed a reasonable amount customarily charged by the clinic for that particular item or service.

(ii) For any one item or service furnished by a Federally qualified health center, the coinsurance liability may not exceed 20 percent of a reasonable amount customarily charged by the center for that particular item or service.

[71 FR 55345, Sept. 22, 2006]

§405.2411 Scope of benefits.

(a) Rural health clinic services reimbursable under this subpart are:

(1) The physicians' services specified in §405.2412;

(2) Services and supplies furnished as an incident to a physician's professional service;

(3) The nurse practitioner or physician assistant services specified in §405.2414;

(4) Services and supplies furnished as an incident to a nurse practitioner's or physician assistant's services; and

(5) Visiting nurse services.

(b) Rural health clinic services are reimbursable when furnished to a patient at the clinic, at a hospital or other medical facility, or at the patient's place of residence.

§405.2412 Physicians' services.

(a) Physicians' services are professional services that are performed by a physician at the clinic or are performed away from the clinic by a physician whose agreement with the clinic provides that he or she will be paid by the clinic for such services.

§405.2413 Services and supplies incident to a physician's services.

(a) Services and supplies incident to a physician's professional service are reimbursable under this subpart if the service or supply is:

(1) Of a type commonly furnished in physicians' offices;

(2) Of a type commonly rendered either without charge or included in the rural health clinic's bill;

(3) Furnished as an incidental, although integral, part of a physician's professional services;

(4) Furnished under the direct, personal supervision of a physician; and

(5) In the case of a service, furnished by a member of the clinic's health care staff who is an employee of the clinic.

(b) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

§405.2414 Nurse practitioner and physician assistant services.

(a) Professional services are reimbursable under this subpart if:

(1) Furnished by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner who is employed by, or receives compensation from, the rural health clinic;

(2) Furnished under the medical supervision of a physician;

(3) Furnished in accordance with any medical orders for the care and treatment of a patient prepared by a physician;

(4) They are of a type which the nurse practitioner, physician assistant, nurse midwife or specialized nurse practitioner who furnished the service is legally permitted to perform by the

State in which the service is rendered; and

(5) They would be covered if furnished by a physician.

(b) The physician supervision requirement is met if the conditions specified in §491.8(b) of this chapter and any pertinent requirements of State law are satisfied.

(c) The services of nurse practitioners, physician assistants, nurse midwives or specialized nurse practitioners are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

§ 405.2415 Services and supplies incident to nurse practitioner and physician assistant services.

(a) Services and supplies incident to a nurse practitioner's or physician assistant's services are reimbursable under this subpart if the service or supply is:

(1) Of a type commonly furnished in physicians' offices;

(2) Of a type commonly rendered either without charge or included in the rural health clinic's bill;

(3) Furnished as an incidental, although integral part of professional services furnished by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner;

(4) Furnished under the direct, personal supervision of a nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner or a physician; and

(5) In the case of a service, furnished by a member of the clinic's health care staff who is an employee of the clinic.

(b) The direct personal supervision requirement is met in the case of a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner only if such a person is permitted to supervise such services under the written policies governing the rural health clinic.

(c) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

§ 405.2416 Visiting nurse services.

(a) Visiting nurse services are covered if:

(1) The rural health clinic is located in an area in which the Secretary has determined that there is a shortage of home health agencies;

(2) The services are rendered to a homebound individual;

(3) The services are furnished by a registered nurse, licensed practical nurse, or licensed vocational nurse who is employed by, or receives compensation for the services from the clinic; and

(4) The services are furnished under a written plan of treatment that is:

(i) Established and reviewed at least every 60 days by a supervising physician of the rural health clinic or established by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner and reviewed at least every 60 days by a supervising physician; and

(ii) Signed by the nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner, or the supervising physician of the clinic.

(b) The nursing care covered by this section includes:

(1) Services that must be performed by a registered nurse, licensed practical nurse, or licensed vocational nurse if the safety of the patient is to be assured and the medically desired results achieved; and

(2) Personal care services, to the extent covered under Medicare as home health services. These services include helping the patient to bathe, to get in and out of bed, to exercise and to take medications.

(c) This benefit does not cover household and housekeeping services or other services that would constitute custodial care.

(d) For purposes of this section, *homebound* means an individual who is permanently or temporarily confined to his or her place of residence because of a medical or health condition. The individual may be considered homebound if he or she leaves the place of residence infrequently. For this purpose, ''place of residence'' does not include a hospital or long term care facility.

§405.2417 Visiting nurse services: Determination of shortage of agencies.

A shortage of home health agencies exists if the Secretary determines that the rural health clinic:

(a) Is located in a county, parish, or similar geographic area in which there is no participating home health agency or adequate home health services are not available to patients of the rural health clinic;

(b) Has (or expects to have) patients whose permanent residences are not within the area serviced by a participating home health agency; or

(c) Has (or expects to have) patients whose permanent residences are not within a reasonable traveling distance, based on climate and terrain, of a participating home health agency.

FEDERALLY QUALIFIED HEALTH CENTER SERVICES

SOURCE: 57 FR 24978, June 12, 1992, unless otherwise noted.

§405.2430 Basic requirements.

(a) *Filing procedures.* (1) In response to a request from an entity that wishes to participate in the Medicare program, CMS enters into an agreement with an entity when—

(i) PHS recommends that the entity qualifies as a Federally qualified health center;

(ii) The Federally qualified health center assures CMS that it meets the Federally qualified health center requirements specified in this subpart and part 491, as described in §405.2434(a); and

(iii) The FQHC terminates other provider agreements, unless the FQHC assures CMS that it is not using the same space, staff and resources simultaneously as a physician's office or another type of provider or supplier. A corporate entity may own other provider types as long as the provider types are distinct from the FQHC.

(2) CMS sends the entity a written notice of the disposition of the request.

(3) When the requirement of paragraph (a)(1) of this section is satisfied, CMS sends the entity two copies of the agreement. The entity must sign and return both copies of the agreement to CMS.

(4) If CMS accepts the agreement filed by the Federally qualified health center, CMS returns to the center one copy of the agreement with the notice of acceptance specifying the effective date (see §489.11), as determined under §405.2434.

(b) *Recommendations by PHS about Federally qualified health centers.* (1) An entity must—

(i) Meet the applicable requirements of the PHS Act, as specified in §405.2401(b); and

(ii) Be recommended by PHS to CMS as a Federally qualified health center.

(2) The PHS notifies CMS of entities that meet the requirements specified in §405.2401(b).

(c) *Provider-based and freestanding Federally qualified health centers.* The requirements and benefits under Medicare for provider-based or freestanding Federally qualified health centers are the same, except that payment methodologies differ, as described in §405.2462.

(d) *Appeals.* An entity is entitled to a hearing in accordance with part 498 of this chapter when CMS fails to enter into an agreement with the entity.

[57 FR 24978, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§405.2434 Content and terms of the agreement.

Under the agreement, the Federally qualified health center must agree to the following:

(a) *Maintain compliance with the requirements.* (1) The Federally qualified health center must agree to maintain compliance with the Federally qualified health center requirements set forth in this subpart and part 491, except that the provisions of §491.3 do not apply.

(2) Centers must promptly report to CMS any changes that result in noncompliance with any of these requirements.

(b) *Effective date of agreement.* (1) Except as specified in paragraph (b)(2) of this section, the effective date of the agreement is the date CMS accepts the signed agreement, which assures that all Federal requirements are met.

(2) For facilities that met all requirements on October 1, 1991, the effective

date of the agreement can be October 1, 1991.

(c) *Charges to beneficiaries.* (1) The beneficiary is responsible for payment of a coinsurance amount which is 20 percent of the amount of Part B payment made to the Federally qualified health center for the covered services. There is no coinsurance for a second or third opinion obtained in accordance with section 1164 of the Act or for pneumococcal vaccine and its administration.

(2) The beneficiary is responsible for blood deductible expenses, as specified in § 410.161.

(3) The Federally qualified health center agrees not to charge the beneficiary (or any other person acting on behalf of a beneficiary) for any Federally qualified health center services for which the beneficiary is entitled to have payment made on his or her behalf by the Medicare program (or for which the beneficiary would have been entitled if the Federally qualified health center had filed a request for payment in accordance with § 410.165 of this chapter), except for coinsurance amounts.

(4) The Federally qualified health center may charge the beneficiary for items and services that are not Federally qualified health center services. However, if the item or service is covered under Part B of Medicare, and the Federally qualified health center agrees to receive Part B payment under the assignment method, the Federally qualified health center may not charge the beneficiary more than 20 percent of the Part B payment.

(d) *Refunds to beneficiaries.* (1) The Federally qualified health center must agree to refund as promptly as possible any money incorrectly collected from Medicare beneficiaries or from someone on their behalf.

(2) As used in this section, ''money incorrectly collected'' means any amount for covered services that is greater than the amount for which the beneficiary was liable because of the coinsurance requirements specified in part 410, subpart E.

(3) Amounts also are considered incorrectly collected if the Federally qualified health center believed the beneficiary was not entitled to Medicare benefits but—

(i) The beneficiary was later determined to have been so entitled;

(ii) The beneficiary's entitlement period fell within the time the Federally qualified health center's agreement with CMS was in effect; and

(iii) The amounts exceed the beneficiary's coinsurance liability.

(e) *Treatment of beneficiaries.* (1) The Federally qualified health center must agree to accept Medicare beneficiaries for care and treatment.

(2) The Federally qualified health center may not impose any limitations with respect to care and treatment of Medicare beneficiaries that it does not also impose upon all other persons seeking care and treatment from the Federally qualified health center. Failure to comply with this requirement is a cause for termination of the Federally qualified health center's agreement with CMS in accordance with § 405.2436(d).

(3) If the Federally qualified health center does not furnish treatment for certain illnesses and conditions to patients who are not Medicare beneficiaries, it need not furnish such treatment to Medicare beneficiaries.

§ 405.2436 Termination of agreement.

(a) *Termination by Federally qualified health center.* The Federally qualified health center may terminate its agreement by—

(1) Filing with CMS a written notice stating its intention to terminate the agreement; and

(2) Notifying CMS of the date on which the Federally qualified health center requests that the termination take effect.

(b) *Effective date.* (1) Upon receiving a Federally qualified health center's notice of intention to terminate the agreement, CMS will set a date upon which the termination takes effect. This effective date may be—

(i) The date proposed by the Federally qualified health center in its notice of intention to terminate, if that date is acceptable to CMS; or

(ii) Except as specified in paragraph (2) of this section, a date set by CMS, which is no later than 6 months after the date CMS receives the Federally

qualified health center's notice of intention to terminate.

(2) The effective date of termination may be less than 6 months following CMS's receipt of the Federally qualified health center's notice of intention to terminate if CMS determines that termination on such a date would not—

(i) Unduly disrupt the furnishing of Federally qualified health center services to the community; or

(ii) Otherwise interfere with the effective and efficient administration of the Medicare program.

(3) The termination is effective at the end of the last day of business as a Federally qualified health center.

(c) *Termination by CMS.* (1) CMS may terminate an agreement with a Federally qualified health center if it finds that the Federally qualified health center—

(i) No longer meets the requirements specified in this subpart; or

(ii) Is not in substantial compliance with—

(A) The provisions of the agreement; or

(B) The requirements of this subpart, any other applicable regulations of this part, or any applicable provisions of title XVIII of the Act.

(2) *Notice by CMS.* CMS will notify the Federally qualified health center in writing of its intention to terminate an agreement at least 15 days before the effective date stated in the written notice.

(3) *Appeal.* A Federally qualified health center may appeal CMS's decision to terminate the agreement in accordance with part 498 of this chapter.

(d) *Effect of termination.* When a Federally qualified health center's agreement is terminated whether by the Federally qualified health center or CMS, payment will not be available for Federally qualified health center services furnished on or after the effective date of termination.

§ 405.2440 Conditions for reinstatement after termination by CMS.

When CMS has terminated an agreement with a Federally qualified health center, CMS will not enter into another agreement with the Federally qualified health center to participate in the Medicare program unless CMS—

(a) Finds that the reason for the termination no longer exists; and

(b) Is assured that the reason for the termination of the prior agreement will not recur.

§ 405.2442 Notice to the public.

(a) When the Federally qualified health center voluntarily terminates the agreement and an effective date is set for the termination, the Federally qualified health center must notify the public prior to a prospective effective date or on the actual day that business ceases, if no prospective date of termination has been set, through publication in at least one newspaper in general circulation in the area serviced by the Federally qualified health center of the—

(1) Effective date of termination of the provision of services; and

(2) Effect of termination of the agreement.

(b) When CMS terminates the agreement, CMS will notify the public through publication in at least one newspaper in general circulation in the Federally qualified health center's service area.

§ 405.2444 Change of ownership.

(a) *What constitutes change of ownership*—(1) *Incorporation.* The incorporation of an unincorporated FQHC constitutes change of ownership.

(2) *Merger.* The merger of the center corporation into another corporation, or the consolidation of two or more corporations, one of which is the center corporation, resulting in the creation of a new corporation, constitutes a change of ownership. (The merger of another corporation into the center corporation does not constitute change of ownership.)

(3) *Leasing.* The lease of all or part of an entity constitutes a change of ownership of the leased portion.

(b) *Notice to CMS.* A center which is contemplating or negotiating change of ownership must notify CMS.

(c) *Assignment of agreement.* When there is a change of ownership as specified in paragraph (a) of this section, the agreement with the existing center is automatically assigned to the new

owner if it continues to meet the conditions to be a Federally qualified health center.

(d) *Conditions that apply to assigned agreements.* An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued including, but not limited to, the following:

(1) Compliance with applicable health and safety standards.

(2) Compliance with the ownership and financial interest disclosure requirements of part 420, subpart C of this subchapter.

§ 405.2446 Scope of services.

(a) For purposes of this section, the terms *rural health clinic* and *clinic* when they appear in the cross references in paragraph (b) of this section also mean Federally qualified health centers.

(b) FQHC services that are paid for under this subpart are outpatient services that include the following:

(1) Physician services specified in § 405.2412.

(2) Services and supplies furnished as an incident to a physician's professional services, as specified in § 405.2413.

(3) Nurse practitioner or physician assistant services specified in § 405.2414.

(4) Services and supplies furnished as an incident to a nurse practitioner or physician assistant services, as specified in § 405.2415.

(5) Clinical psychologist and clinical social worker services specified in § 405.2450.

(6) Services and supplies furnished as an incident to a clinical psychologist or clinical social worker services, as specified in § 405.2452.

(7) Visiting nurse services specified in § 405.2416.

(8) Nurse-midwife services specified in § 405.2401.

(9) Preventive primary services specified in § 405.2448 of this subpart.

(10) Medical nutrition therapy services as specified in part 410, subpart G of this chapter, and diabetes outpatient self-management training services as specified in part 410, subpart H of this chapter.

(c) Federally qualified health center services are covered when provided in outpatient settings only, including a patient's place of residence, which may be a skilled nursing facility or a nursing facility or other institution used as a patient's home.

(d) Federally qualified health center services are not covered in a hospital, as defined in section 1861(e)(1) of the Act.

[57 FR 24979, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996; 71 FR 69782, Dec. 1, 2006]

§ 405.2448 Preventive primary services.

(a) Preventive primary services are those health services that—

(1) A center is required to provide as preventive primary health services under section 329, 330, and 340 of the Public Health Service Act;

(2) Are furnished by or under the direct supervision of a nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner, clinical psychologist, clinical social worker, or a physician;

(3) In the case of a service, are furnished by a member of the center's health care staff who is an employee of the center or by a physician under arrangements with the center; and

(4) Except as specifically provided in section 1861(s) of the Act, include only drugs and biologicals that cannot be self-administered.

(b) Preventive primary services which may be paid for when provided by Federally qualified health centers are the following:

(1) Medical social services.

(2) Nutritional assessment and referral.

(3) Preventive health education.

(4) Children's eye and ear examinations.

(5) Prenatal and post-partum care.

(6) Perinatal services.

(7) Well child care, including periodic screening.

(8) Immunizations, including tetanus-diptheria booster and influenza vaccine.

(9) Voluntary family planning services.

(10) Taking patient history.

(11) Blood pressure measurement.

(12) Weight.

(13) Physical examination targeted to risk.

(14) Visual acuity screening.
(15) Hearing screening.
(16) Cholesterol screening.
(17) Stool testing for occult blood.
(18) Dipstick urinalysis.
(19) Risk assessment and initial counseling regarding risks.
(20) Tuberculosis testing for high risk patients.
(21) For women only.
(i) Clinical breast exam.
(ii) Referral for mammography; and
(iii) Thyroid function test.

(c) Preventive primary services do not include group or mass information programs, health education classes, or group education activities, including media productions and publications.

(d) Screening mammography is not considered a Federally qualified health center service, but may be provided at a Federally qualified health center if the center meets the requirements applicable to that service specified in §410.34 of this subchapter. Payment is made under applicable Medicare requirements.

(e) Preventive primary services do not include eyeglasses, hearing aids, or preventive dental services.

[57 FR 24980, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§405.2450 Clinical psychologist and clinical social worker services.

(a) For clinical psychologist or clinical social worker professional services to be payable under this subpart, the services must be—

(1) Furnished by an individual who owns, is employed by, or furnishes services under contract to the FQHC;

(2) Of a type that the clinical psychologist or clinical social worker who furnishes the services is legally permitted to perform by the State in which the service is furnished;

(3) Performed by a clinical social worker or clinical psychologist who is legally authorized to perform such services under State law or the State regulatory mechanism provided by the law of the State in which such services are performed; and

(4) Covered if furnished by a physician.

(b) If State law prescribes a physician supervision requirement, it is met if the conditions specified in §491.8(b) of this chapter and any pertinent requirements of State law are satisfied.

(c) The services of clinical psychologists or clinical social workers are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

[57 FR 24980, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§405.2452 Services and supplies incident to clinical psychologist and clinical social worker services.

(a) Services and supplies incident to a clinical psychologist's or clinical social worker's services are reimbursable under this subpart if the service or supply is—

(1) Of a type commonly furnished in a physician's office;

(2) Of a type commonly furnished either without charge or included in the Federally qualified health center's bill;

(3) Furnished as an incidental, although integral part of professional services furnished by a clinical psychologist or clinical social worker;

(4) Furnished under the direct, personal supervision of a clinical psychologist, clinical social worker or physician; and

(5) In the case of a service, furnished by a member of the center's health care staff who is an employee of the center.

(b) The direct personal supervision requirement in paragraph (a)(4) of this section is met only if the clinical psychologist or clinical social worker is permitted to supervise such services under the written policies governing the Federally qualified health center.

PAYMENT FOR RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES

SOURCE: 57 FR 24976, 24977, June 12, 1992, unless otherwise noted.

§405.2460 Applicability of general payment exclusions.

The payment conditions, limitations, and exclusions set out in subpart C of this part, part 410 and part 411 of this chapter are applicable to payment for

services provided by rural health clinics and Federally qualified health centers, except that preventive primary services, as defined in §405.2448, are covered in Federally qualified health centers and not excluded by the provisions of section 1862(a) of the Act.

§ 405.2462 Payment for rural health clinic and Federally qualified health center services.

(a) *Payment to provider-based rural health clinics and Federally qualified health centers.* A rural health clinic or Federally qualified health center is paid in accordance with parts 405 and 413 of this subchapter, as applicable, if—

(1) The clinic or center is an integral and subordinate part of a hospital, skilled nursing facility or home health agency participating in Medicare (that is, a provider of services); and

(2) The clinic or center is operated with other departments of the provider under common licensure, governance and professional supervision.

(b) *Payment to independent rural health clinics and freestanding Federally qualified health centers.* (1) All other clinics and centers will be paid on the basis of an all-inclusive rate for each beneficiary visit for covered services. This rate will be determined by the intermediary, in accordance with this subpart and general instructions issued by CMS.

(2) The amount payable by the intermediary for a visit will be determined in accordance with paragraphs (b)(3) and (4) of this section.

(3) *Federally qualified health centers.* For Federally qualified health center visits, Medicare will pay 80 percent of the all-inclusive rate since no deductible is applicable to Federally qualified health center services.

(4) *Rural health clinics.* (i) If the deductible has been fully met by the beneficiary prior to the rural health clinic visit, Medicare pays 80 percent of the all-inclusive rate.

(ii) If the deductible has not been fully met by the beneficiary before the visit, and the amount of the clinic's reasonable customary charge for the services that is applied to the deductible is—

(A) Less than the all-inclusive rate, the amount applied to the deductible will be subtracted from the all-inclusive rate and 80 percent of the remainder, if any, will be paid to the clinic;

(B) Equal to or exceeds the all-inclusive rate, no payment will be made to the clinic.

(5) To receive payment, the clinic or center must follow the payment procedures specified in §410.165 of this chapter.

(6) Payment for treatment of mental psychoneurotic or personality disorders is subject to the limitations on payment in §410.155(c).

[71 FR 55345, Sept. 22, 2006]

§ 405.2463 What constitutes a visit.

(a) *Visit*—(1) *General.* (i) For rural health clinics, a visit is a face-to-face encounter between a clinic or center patient and a physician, physician assistant, nurse practitioner, nurse midwife, visiting nurse, clinical psychologist, or clinical social worker.

(ii) For FQHCs, a visit is—

(A) A face-to-face encounter, as described in paragraph (a)(1)(i) of this section; or

(B) A face-to-face encounter between a patient and a qualified provider of medical nutrition therapy services as defined in part 410, subpart G of this chapter; or a qualified provider of outpatient diabetes self-management training services as defined in part 410, subpart H of this chapter.

(2) *Medical visit.* A medical visit is a face-to-face encounter between a clinic or center patient and a physician, physician assistant, nurse practitioner, nurse midwife, or a visiting nurse; and for FQHCs only, a medical visit also includes a separately billable medical nutrition therapy visit or a diabetes outpatient self-management training visit.

(3) *Other health visit.* An other health visit is a face-to-face encounter between a clinic or center patient and a clinical psychologist, clinical social worker, or other health professional for mental health services.

(b) *Encounters.* Encounters with more than one health professional and multiple encounters with the same health professional that take place on the

same day and at a single location constitute a single visit, except when one of the following conditions exist:

(1) After the first encounter, the patient suffers illness or injury requiring additional diagnosis or treatment.

(2) The patient has a medical visit and other health visit(s), as defined in paragraph (a) of this section.

(c) *Payment.* Medicare pays for more than one visit per day when the conditions in paragraph (b) of this section are met or a separate visit under paragraph (a)(1)(ii)(B) of this section is made.

[71 FR 69782, Dec. 1, 2006]

§405.2464 All-inclusive rate.

(a) *Determination of rate.* (1) An all-inclusive rate is determined by the intermediary at the beginning of the reporting period.

(2) The rate is determined by dividing the estimated total allowable costs by estimated total visits for rural health clinic or Federally qualified health center services.

(3) The rate determination is subject to any tests of reasonableness that may be established in accordance with this subpart.

(b) *Adjustment of rate.* (1) The intermediary, during each reporting period, periodically reviews the rate to assure that payments approximate actual allowable costs and visits for rural health clinic or Federally qualified health center services and adjusts the rate if:

(i) There is a significant change in the utilization of clinic or center services;

(ii) Actual allowable costs vary materially from the clinic or center's allowable costs; or

(iii) Other circumstances arise which warrant an adjustment.

(2) The clinic or center may request the intermediary to review the rate to determine whether adjustment is required.

§405.2466 Annual reconciliation.

(a) *General.* Payments made to a rural health clinic or a Federally qualified health center during a reporting period are subject to reconciliation to assure that those payments do not exceed or fall short of the allowable costs attributable to covered services furnished to Medicare beneficiaries during that period.

(b) *Calculation of reconciliation.* (1) The total reimbursement amount due the clinic or center for covered services furnished to Medicare beneficiaries is based on the report specified in §405.2470(c)(2) and is calculated by the intermediary as follows:

(i) The average cost per visit is calculated by dividing the total allowable cost incurred for the reporting period by total visits for rural health clinic or Federally qualified health center services furnished during the period. The average cost per visit is subject to tests of reasonableness which may be established in accordance with this subpart.

(ii) The total cost of rural health clinic or Federally qualified health center services furnished to Medicare beneficiaries is calculated by multiplying the average cost per visit by the number of visits for covered rural health clinic or Federally qualified health center services by beneficiaries.

(iii) For rural health clinics, the total reimbursement due the clinic is 80 percent of the amount calculated by subtracting the amount of deductible incurred by beneficiaries that is attributable to rural health clinic services from the cost of these services. The reimbursement computation for Federally qualified health centers does not include a reduction related to the deductible because Federally qualified health center services are not subject to a deductible.

(iv) For rural health clinics and FQHCs, payment for pneumococcal and influenza vaccine and their administration is 100 percent of Medicare reasonable cost.

(2) The total reimbursement amount due is compared with total payments made to the clinic or center for the reporting period, and the difference constitutes the amount of the reconciliation.

(c) *Notice of program reimbursement.* The intermediary sends written notice to the clinic or center:

(1) Setting forth its determination of the total reimbursement amount due the clinic or center for the reporting

period and the amount, if any, of the reconciliation; and

(2) Informing the clinic or center of its right to have the determination reviewed at a hearing under the procedures set forth in subpart R of this part.

(d) *Payment of reconciliation amount*—(1) *Underpayments.* If the total reimbursement due the clinic or center exceeds the payments made for the reporting period, the intermediary makes a lump-sum payment to the clinic or center to bring total payments into agreement with total reimbursement due the clinic or center.

(2) *Overpayments.* If the total payments made to a clinic or center for the reporting period exceed the total reimbursement due the clinic or center for the period, the intermediary arranges with the clinic or center for repayment through a lump-sum refund, or, if that poses a hardship for the clinic or center, through offset against subsequent payments or a combination of offset and refund. The repayment must be completed as quickly as possible, generally within 12 months from the date of the notice of program reimbursement. A longer repayment period may be agreed to by the intermediary if the intermediary is satisfied that unusual circumstances exist which warrant a longer period.

[57 FR 24976, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§ 405.2468 Allowable costs.

(a) *Applicability of general Medicare principles.* In determining whether and to what extent a specific type or item of cost is allowable, such as interest, depreciation, bad debts and owner compensation, the intermediary applies the principles for reimbursement of provider costs, as set forth in part 413 of this subchapter.

(b) *Typical rural health clinic and Federally qualified health center costs.* The following types and items of cost are included in allowable costs to the extent that they are covered and reasonable:

(1) Compensation for the services of a physician, physician assistant, nurse practitioner, nurse-midwife, visiting nurse, qualified clinical psychologist, and clinical social worker who owns, is employed by, or furnishes services under contract to an FQHC. (RHCs are not paid for services furnished by contracted individuals other than physicians.)

(2) Compensation for the duties that a supervising physician is required to perform under the agreement specified in § 491.8 of this chapter.

(3) Costs of services and supplies incident to the services of a physician, physician assistant, nurse practitioner, nurse-midwife, qualified clinical psychologist, or clinical social worker.

(4) Overhead costs, including clinic or center administration, costs applicable to use and maintenance of the entity, and depreciation costs.

(5) Costs of services purchased by the clinic or center.

(c) *Tests of reasonableness for rural health clinic cost and utilization.* Tests of reasonableness authorized by sections 1833(a) and 1861(v)(1)(A) of the Act may be established by CMS or the carrier with respect to direct or indirect overall costs, costs of specific items and services, or costs of groups of items and services. Those tests include, but are not limited to, screening guidelines and payment limitations.

(d) *Screening guidelines.* (1) Costs in excess of amounts established by the guidelines are not included unless the clinic or center provides reasonable justification satisfactory to the intermediary.

(2) Screening guidelines are used to assess the costs of services, including the following:

(i) Compensation for the professional and supervisory services of physicians and for the services of physician assistants, nurse practitioners, and nurse-midwives.

(ii) Services of physicians, physician assistants, nurse practitioners, nurse-midwives, visiting nurses, qualified clinical psychologists, and clinical social workers.

(iii) The level of administrative and general expenses.

(iv) Staffing (for example, the ratio of other clinic or center personnel to physicians, physician assistants, and nurse practitioners).

(v) The reasonableness of payments for services purchased by the clinic or center, subject to the limitation that

the costs of physician services purchased by the clinic or center may not exceed amounts determined under the applicable provisions of subpart E of part 405 or part 415 of this chapter.

(e) *Payment limitations.* Limits on payments may be set by CMS, on the basis of costs estimated to be reasonable for the provision of such services.

(f) *Graduate medical education.* (1) Effective for that portion of cost reporting periods occurring on or after January 1, 1999, if an RHC or an FQHC incurs ''all or substantially all'' of the costs for the training program in the nonhospital setting as defined in §413.75(b) of this chapter, the RHC or FQHC may receive direct graduate medical education payment for those residents.

(2) Direct graduate medical education costs are not included as allowable cost under §405.2466(b)(1)(i); and therefore, are not subject to the limit on the all-inclusive rate for allowable costs.

(3) Allowable graduate medical education costs must be reported on the RHC's or the FQHC's cost report under a separate cost center.

(4) Allowable graduate medical education costs are non-reimbursable if payment for these costs are received from a hospital or a Medicare+Choice organization.

(5) Allowable direct graduate medical education costs under paragraphs (f)(6) and (f)(7)(i) of this section, are subject to reasonable cost principles under part 413 and the reasonable compensation equivalency limits in §§415.60 and 415.70 of this chapter.

(6) The allowable direct graduate medical education costs are those costs incurred by the nonhospital site for the educational activities associated with patient care services of an approved program, subject to the redistribution and community support principles in §413.85(c).

(i) The following costs are allowable direct graduate medical education costs to the extent that they are reasonable—

(A) The costs of the residents' salaries and fringe benefits (including travel and lodging expenses where applicable).

(B) The portion of teaching physicians' salaries and fringe benefits that are related to the time spent teaching and supervising residents.

(C) Facility overhead costs that are allocated to direct graduate medical education.

(ii) The following costs are not allowable graduate medical education costs—

(A) Costs associated with training, but not related to patient care services.

(B) Normal operating and capital-related costs.

(C) The marginal increase in patient care costs that the RHC or FQHC experiences as a result of having an approved program.

(D) The costs associated with activities described in §413.85(h) of this chapter.

(7) Payment is equal to the product of—

(i) The RHC's or the FQHC's allowable direct graduate medical education costs; and

(ii) Medicare's share, which is equal to the ratio of Medicare visits to the total number of visits (as defined in §405.2463).

(8) Direct graduate medical education payments to RHCs and FQHCs made under this section are made from the Federal Supplementary Medical Insurance Trust Fund.

[43 FR 8261, Mar. 1, 1978. Redesignated and amended at 57 FR 24977, June 12, 1992; 60 FR 63176, Dec. 8, 1995; 61 FR 14658, Apr. 3, 1996; 63 FR 41002, July 31, 1998; 66 FR 39932, Aug. 1, 2001; 70 FR 47484, Aug. 12, 2005]

§405.2469 Federally Qualified Health Centers supplemental payments.

Federally Qualified Health Centers under contract (directly or indirectly) with Medicare Advantage organizations are eligible for supplemental payments for covered Federally Qualified Health Center services furnished to enrollees in Medicare Advantage plans offered by the Medicare Advantage organization to cover the difference, if any, between their payments from the Medicare Advantage plan and what they would receive under the cost-based Federally Qualified Health Center payment system.

(a) *Calculation of supplemental payment.* (1) The supplemental payment for Federally Qualified Health Center covered services provided to Medicare patients enrolled in Medicare Advantage plans is based on the difference between—

(i) Payments received by the center from the Medicare Advantage plan as determined on a per visit basis; and

(ii) The Federally Qualified Health Center's all-inclusive cost-based per visit rate as set forth in this subpart, less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act.

(2) Any financial incentives provided to Federally Qualified Health Centers under their Medicare Advantage contracts, such as risk pool payments, bonuses, or withholds, are prohibited from being included in the calculation of supplemental payments due to the Federally Qualified Health Center.

(b) *Per visit supplemental payment.* A supplemental payment required under this section is made to the Federally Qualified Health Center when a covered face-to-face encounter occurs between a Medicare Advantage enrollee and a practitioner as set forth in § 405.2463.

[70 FR 70329, Nov. 21, 2005, as amended at 71 FR 9460, Feb. 24, 2006]

§ 405.2470 Reports and maintenance of records.

(a) *Maintenance and availability of records.* The rural health clinic or Federally qualified health center must:

(1) Maintain adequate financial and statistical records, in the form and containing the data required by CMS, to allow the intermediary to determine payment for covered services furnished to Medicare beneficiaries in accordance with this subpart;

(2) Make the records available for verification and audit by HHS or the General Accounting Office;

(3) Maintain financial data on an accrual basis, unless it is part of a governmental institution that uses a cash basis of accounting. In the latter case, appropriate depreciation on capital assets is allowable rather than the expenditure for the capital asset.

(b) *Adequacy of records.* (1) The intermediary may suspend reimbursement if it determines that the clinic or center does not maintain records that provide an adequate basis to determine payments under Medicare.

(2) The suspension continues until the clinic or center demonstrates to the intermediary's satisfaction that it does, and will continue to, maintain adequate records.

(c) *Reporting requirements*—(1) *Initial report.* At the beginning of its initial reporting period, the clinic or center must submit an estimate of budgeted costs and visits for rural health clinic or Federally qualified health center services for the reporting period, in the form and detail required by CMS, and such other information as CMS may require to establish the payment rate.

(2) *Annual reports.* Within 90 days after the end of its reporting period, the clinic or center must submit, in such form and detail as may be required by CMS, a report of:

(i) Its operations, including the allowable costs actually incurred for the period and the actual number of visits for rural health clinic or Federally qualified health center services furnished during the period; and

(ii) The estimated costs and visits for rural health clinic services or Federally qualified health center services for the succeeding reporting period and such other information as CMS may require to establish the payment rate.

(3) *Late reports.* If the clinic or center does not submit an adequate annual report on time, the intermediary may reduce or suspend payments to preclude excess payment to the clinic or center.

(4) *Inadequate reports.* If the clinic or center does not furnish a report or furnishes a report that is inadequate for the intermediary to make a determination of program payment, CMS may deem all payments for the reporting period to be overpayments.

(5) *Postponement of due date.* For good cause shown by the clinic or center, the intermediary may, with CMS's approval, grant a 30-day postponement of the due date for the annual report.

(6) *Reports following termination of agreement or change of ownership.* The report from a clinic or center which voluntarily or involuntarily ceases to participate in the Medicare program or experiences a change in ownership (see §§ 405.2436–405.2438) is due no later than

45 days following the effective date of the termination of agreement or change of ownership.

§ 405.2472 Beneficiary appeals.

A beneficiary may request a hearing by an intermediary (subject to the limitations and conditions set forth in subpart H of this part) if:

(a) The beneficiary is dissatisfied with an intermediary's determination denying a request for payment made on his or her behalf by a rural health clinic or Federally qualified health center; or

(b) The beneficiary is dissatisfied with the amount of payment; or

(c) The beneficiary believes the request for payment is not being acted upon with reasonable promptness.

[43 FR 8261, Mar. 1, 1978. Redesignated and amended at 57 FR 24978, June 12, 1992]

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

Subpart A—General Provisions

Sec.

Subpart B—Hospital Insurance Without Monthly Premiums

Subpart C—Premium Hospital Insurance

Subpart D—Special Circumstances That Affect Entitlement to Hospital Insurance

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 48 FR 12536, Mar. 25, 1983, unless otherwise noted. Redesignated at 51 FR 41338, Nov. 14, 1986.

Subpart A—General Provisions

§ 406.1 Statutory basis.

Sections 226, 226A, 1818 and 1818A of the Social Security Act and section 103 of Public Law 89–97 establish the conditions for entitlement to hospital insurance benefits. Sections 202 (t) and (u) of the Act specify limitations that apply to certain aliens and to persons convicted of certain offenses.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986, as amended at 56 FR 38078, Aug. 12, 1991]

§ 406.2 Scope.

Subparts A through D of this part specify the conditions of eligibility for hospital insurance and set forth certain specific conditions that affect entitlement to benefits. Hospital insurance is authorized under Part A of title XVIII and is also referred to as Medicare Part A. It includes inpatient hospital care, posthospital SNF care, home health services, and hospice care.

[48 FR 56026, Dec. 16, 1983, as amended at 50 FR 33033, Aug. 16, 1985. Redesignated and amended at 51 FR 41338, Nov. 14, 1986]

§ 406.3 Definitions.

First month of eligibility means the first month in which an individual meets all the requirements for entitlement to hospital insurance except application or enrollment if that is required.